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Supporting Innovation: A Policy Study

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Cambridge

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SUPPORTING INNOVATION:
A POLICY STUDY

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REGULATORY IMPACTS BRANCH
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WASHINGTON, D.C. 20460

U.S. ENVIRONMENTAL PROTECTION AGENCY
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WASHINGTON, D.C. 20460

DISCLAIMER

This document is a contractor's study done with the supervision and review of the Office of Pesticides and Toxic Substances of the U.S. Environmental Protection Agency. The purpose of the study was to develop and evaluate policies to support innovation in the chemical industries.

The report was submitted in fulfillment of Task Order 1 of Contract Number 68-01-5878 by the subcontractor, MIT's Center for Policy Alternatives. Work was completed in August 1980.

The study is not an official EPA publication. The document can not be cited, referenced, or represented in any court proceedings as a statement of EPA's view regarding the chemical industries, or the impact of the regulations implementing TSCA.

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1. EXECUTIVE SUMMARY

1.1 The Background and Purpose of the Report

After several years of debate the Toxic Substances Control Act (TSCA) was enacted into law in 1976. Its purpose is to protect health and the environment from unreasonable risk of injury resulting from the production, use and disposal of chemical substances. The Act was designed to fill the gaps in existing regulation of toxic substances by establishing a framework within which new chemical substances can be assessed for potential hazard before they are marketed and widely distributed, and by establishing a structure that broadens the authority of EPA to regulate existing and new chemicals.

The framers of this legislation recognized that it had the potential to influence the process and the outcomes of technological innovation in the chemical and related industries. Therefore, the Act states at Section 2(b)(3):

> Authority over chemical substances and mixtures should be exercised in such a manner as not to impede unduly or create unnecessary economic barriers to technolgical innovation while fulfilling the primary purpose of this Act to assure that such innovation and commerce in such chemical substances and mixtures do not present an unreasonable risk of injury to health or the environment.

The concern for innovation has a number of origins. First, a major purpose of the Act is that the industries involved should be encouraged to develop and market safer, more healthful new chemicals that can substitute for existing hazardous chemicals now on the market. Thus, the law encourages a systematic shift in industry priorities for new product development. Second, the development and marketing of new chemical products is the basis for the historic pattern of rapid growth in the chemical industry and for its contributions to meeting social needs and to the growth of the economy. Innovation in these industries includes not only a wide variety of minor variations on existing chemicals, but also major new chemicals that can address social problems or that might be the basis for future industry growth. In this regard, Section 2(c) makes clear that Congress is concerned that EPA carry out the Act with due regard for its environmental, economic and social impacts - an indication of concern for the economic strength of the industry and for its contributions to society.

The purpose of the present project is to design, analyze, and assess alternative policies that might be used to address the problems TSCA might create for innovation, while maintaining the dominant thrust of TSCA to protect health and the environment from unreasonable risk of injury and disease. Such policies might be implemented by EPA through administrative actions, or they might require Congressional action to amend the Act or to establish new complementary authorities elsewhere in EPA or other government agencies. The ongoing policy discussions and the literature on technological innovation yield many suggestions of such policy options, and a major concern of this research has been to assess and analyze the potential of those options to contribute to the solution of the problem at hand in a cost-effective and responsible manner.

1.2 Effects of TSCA Regulation on Chemical Innovation

It is useful to think of technological innovation as a process whose outcomes are new, commercially successful products, processes, systems or services. The process involves inputs of human and financial resources to such activities as research, invention, development, testing, marketing and diffusion.

There is not a good understanding of the nature and sources of chemical innovation. For example, there are no sound data on the number of new chemicals marketed each year, or on the contributions of small and large firms or new entrants to chemical innovation. A few studies have found that large firms are more innovative than small ones, but even these results are open to serious question. A variety of factors in the scientific, financial and competitive environment of the chemical industry are changing, and even if TSCA had not been passed historic trends in chemical innovation are unlikely to be followed in the future. Contributing to this is the fact that developments in products liability and in other environmental and occupational health and safety regulation are influencing chemical innovation quite apart from TSCA's effects.

Superimposed on the uncertain future of chemical innovation are the variety of effects that the TSCA regulatory requirements may have.* Environmental, health, and safety regulation can act through a variety of mechanisms to inhibit, stimulate or redirect technological innovation, depending on the circumstances. Since TSCA features several different regulatory stimuli, and since the "chemical industry" is in fact a combination of many very different kinds of industries in various stages of maturity whose products differ greatly in the hazards they present; it is to be expected that inhibition, stimulation, and redirection will all occur at the same time. However, the current understanding of the interaction of regulation and innovation does not allow one to predict the quantitative impact of TSCA on the rate of chemical product innovation.

The inhibition of innovation by TSCA could arise, for example, from the marketing delays, testing costs, resource diversion, and commercial uncertainties it would introduce into the innovation process. The stimulation of innovation could arise, for example, from the increased staff diversity and revised corporate decision-making process required to comply with TSCA. Redirection could arise from firms electing to seek safe substitutes or abandon lines of research into chemicals expected to pose a high risk to health. The inhibition of innovation is more likely to occur in small firms, new entrants, and makers of innovative specialty products, while stimulation is more likely to occur in large, established, mature firms that use highly-integrated process technology.

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*Regulation in this context includes both the procedural requirements such as premanufacturing notification and substantive requirements such as use restrictions or testing requirements.

At the same time, regulation can also stimulate innovation in some small firms and new entrants and inhibit it in some mature firms. Thus, redirection due to TSCA can occur in both the nature and sources of chemical innovation.

The main purposes of TSCA are to slow the rate of introduction and/or encourage the more prudent use and operation of products and processes that pose unreasonable risks of injury to health and the environment. Thus, some inhibition and some re-direction of chemical innovation was expected due to TSCA - it was part of the social bargain struck by Congress. Therefore, an observation that the rate of chemical innovation has declined, or that the nature of chemical innovation has shifted is not, by itself, grounds for determining that EPA has acted "unduly" or "created unnecessary economic barriers to innovation." Offsetting policies should not attempt to return the rate and direction of chemical innovation to some hypothetical pre-TSCA baseline.

Nonetheless, despite EPA's best intentions, the implementation of TSCA may unnecessarily restrict technological innovation. Two concepts, regulatory fine tuning and transition phenomena, can help explain the origins of the unnecessarily restrictive impacts of TSCA on chemical innovation.

First, TSCA gives the Administrator of EPA considerable discretion in carrying out the purpose of the Act. Despite the many special provisions and wide latitude for decision making embodied in the Act, rules to implement TSCA are likely to bear more heavily on some parties than on others in ways which are unnecessary to accomplish the regulatory goals. This is likely to happen as a result of the need to compromise fine tuning of the rules and procedures for political and administrative feasibility. Furthermore, the very complexity of TSCA may cause unnecessary burdens for some regulated parties, such as costs, delays or uncertainties, that would unnecessarily restrict innovation.

Second, when a new law is passed that is intended to influence industrial behavior, a finite period of time elapses while the rules and procedures to implement the law are adopted. During this period, firms and investors may perceive a high level of uncertainty in making business decisions. Also, for a time after the law is passed and implemented, the infrastructure necessary to respond to the law's requirements may not be in place. During this period, newly-regulated firms can be seriously disrupted, and smaller firms may even disappear with the result that innovation declines, even for safer chemicals.

Congress and the agency do not intend to burden industry with these transition phenomena or to use rules and procedures that are inadequately tuned to the needs of industry, yet some problems are inevitable if a vigorous new regulatory program is to be put in place to accomplish the primary goal of controlling unreasonable risk. To the extent that the regulations unduly inhibit or create unnecessary barriers to technological innovation, and to the extent that these undesirable effects can be corrected by policies whose costs are commensurate with the benefits they offer, EPA and/or Congress may wish to take action to put such policies into action.

1.3 Design and Analysis of Policy Options to Offset Unnecessarily Restrictive Impacts of TSCA on Innovation

Based on a comprehensive review of the literature and on a general understanding of the influence of regulation on innovation, thirty-two policy options for offsetting the unnecessarily restrictive impacts of TSCA on chemical innovation were developed. These options, which are discussed in detail in chapter 4, are intended to be widely representative of the possibilities open to government and to reflect the options proposed by various interest groups. Table 1.1 lists the options, categorized by the general approach they use.

The policy options were judged using a structured approach by each of the project team members who rated each of the thirty-two policies on seven separate criteria. The individual judgments were combined into an overall rating of each policy relative to the others. The procedure was

TABLE 1.1 Policy Options for Consideration

Reducing the Cost of New Chemical Development

A. Direct cost subsidy for general new chemical development via grant mechanism.

B. Direct cost subsidy for general new chemical development via loan mechanism (or loan guarantee).

C. Direct cost subsidy for testing/compliance costs of new chemical development via grant mechanism.

D. Direct cost subsidy for testing/compliance costs of new chemical development via loan mechanism (or loan guarantee).

E. Indirect cost subsidy for chemical innovation generally via tax mechanism.

F. Indirect cost subsidy for testing and compliance costs via tax mechanism.

Increasing the Financial Rewards for New Chemicals

G. Increased patent life for new chemicals.

H. Strengthened trade secret protection by limitations on EPA authority to release information.

I. Decreased taxes on sales of new chemicals.

Increase the Availability of Capital for New Chemicals

J. Increased capital availability for new chemical development via government supported venture capital company.

K. Increased capital availability for new chemical development via tax changes or via SEC rules.

Reduce the Commercial Risk Associated with New Chemicals

L. Reduce risk through goverment financed insurance for regulatory losses.

M. Reduce risk through government procurement of new chemicals.

N. Reduce risk from products liability actions by establishing limits on liability.

Reduce the Cost of Testing

O. Establish government testing for TSCA requirements.

TABLE 1.1 Policy Options for Consideration
(continued)

Reallocations of Cost within the Private Sector

- P. Sharing of test data with reimbursement.
- Q. Facilitate private sector joint R&D or joint testing.

Information-based Strategies

- R. EPA dissemination of chemical information--test results and/or labeling.
- S. Chemical technology extension service, including dissemination of information on test and compliance methods.

Changing Market Structure

- T. Antitrust action to favor new, small firms in the chemical industry.
- U. Tax adjustment to favor small firms or new entrants in the chemical industry.

Improving the Technology Necessary for Compliance

- V. Government support to develop new, better test methods.
- W. Government support for education and training programs.

Regulatory Changes

- X. Actions against existing substitutes for new chemicals.
- Y. Fixing time periods for regulatory actions.
- Z. Post-market surveillance of PMN's.
- AA. Regulatory exemptions for low volume, new chemicals.
- BB. Regulatory exemptions for small firms.
- CC. Regulatory exemptions for "low risk" chemicals.
- DD. "Fast track" PMN's for safe and/or major innovations.
- EE. Generic PMN for classes of new chemicals.
- FF. Improve EPA staff capability to assess impact of regulatory actions on innovation.
- GG. "No-intervention" policy; (i.e., no change from existing TSCA regulation).

used to gain semi-quantitative insight into the relative merits of each policy and to stimulate structured discussion of each option by the project team.*

The seven criteria used to formulate the overall policy ratings are:

1. Capacity to countervail
2. Private costs
3. Public costs
4. Administrative feasibility
5. Time to implement
6. Supportive of TSCA's aims
7. Other side effects.

An eighth criterion, political feasibility, was also used, but not in forming the overall ratings. Subsequently, two other criteria were added: criterion 9, "initial policy rating," which is an initial estimate of the overall rating of a policy made without reference to the detailed criteria, and criterion 10, "effectiveness," which represents a combination (the product) of a policy's capacity to countervail and its administrative feasibility.

The question of financing the public costs of each policy was treated separately from assessment of the relative rating of each policy. In general, on-budget financing is regarded as a superior alternative to off-budget financing. On-budget financing is both more predictable and more reviewable than off-budget expenditures. In addition, it fits well within existing budgetary and institutional structures, while off-budget financing often requires the establishment of new institutions. In examining the 32 policy options, the arguments for on-budget financing have appeared to be especially persuasive when the public costs of new programs are small, or when they require little in the way of new institutional structures. Matching the policy and financing options is illustrated in table 1.2. No attempt was made to select the best financing method for each policy option.

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*An economic model could not be used to analyze the options because available models do not adequately address the dynamics of technological innovation, the data needed for such an assessment are lacking, and non-economic-factors such as administrative feasibility and effects on the primary goals of TSCA must be considered.

TABLE 1.2

Matching Policy and Financing Options

Policy	Budgetary Outlays			Off-Budget Outlays			
	Reallocation of Discretionary Funds	New EPA Programs	New Non-EPA Authority	Tax Expenditures	New Taxes	New Financial Entities	Contingent Liabilities
A. Grant Subsidy		X	X		X		
B. Loan Subsidy		X	X		X		
Loan Guarantee							X
C. Testing Grant		X	X		X		
D. Testing Loan		X	X		X		
Testing Loan Guarantee							X
E. General Tax Subsidy				X			
F. Testing Tax Subsidy				X			
G. Patent							
H. Trade Secret							
I. Decreased Taxes				X			
J. Venture Capital Company		X	X		X	X	
K. Increased Capital				X			
L. Insurance		X	X		X	X	X
M. Procurement			X		X		
N. Liability Limits							X
O. Government Testing		X	X		X	X	
P. Sharing Test Data							

TABLE 1.2
continued

Policy	Budgetary Outlays			Off-Budget Outlays			
	Reallocation of Discretionary Funds	New EPA Programs	New Non-EPA Authority	Tax Expenditures	New Taxes	New Financial Entities	Contingent Liabilities
Q. Joint R&D							
R. Information Dissemination	X	X					
S. Technology Extension Service		X	X		X		
T. Antitrust							
U. Tax Adjustments				X			
V. Better Tests	X	X	X		X		
W. Education	X	X	X		X		
X. Action Against Substitutes							
Y. Fixed Time Periods							
Z. Post-Market Surveillance							
AA. Low Volume Exemption							
BB. Small Firm Exemption							
CC. Low Risk Exemption							
DD. Fast-Track							
EE. Generic PMN							
FF. Improve EPA	X	X					

1.4 Results of the Policy Analysis

The 32 policy alternaties are listed in table 1.3 in descending order of their overall rating. These ratings represent the geometric means of the individual ratings assigned by each of the six members of the project team, using the seven criterion model. Very generally, the ratings can be interpreted as indicative of a measure of the ratio of effectiveness to costs for each policy. However, the ratings in table 1.3 have no quantitative significance as benefit/cost or effectiveness/cost ratios, since a rating of 1.0 on each criterion was assigned to an arbitrarily chosen option, against which the other options were compared..

The ratings range from a high of 1.212 for the top ranking policy to a low of 0.175 for the lowest ranking policy. There is a sharp drop in ratings around the seventh ranked policy, and policies R, EE, V, C, DD, W, and D appear to be substantially superior to the others overall.

Policies that rank highest overall do so by virtue of a combination of their weighted ratings on several criteria, so it is not necessary for them to rank high on all criteria. (Table 1.4 shows the rank orders of the seven highest ranking options on each of the criteria.) For example, each high ranking policy alone is not able to offset the unnecessarily restrictive impacts of TSCA on innovation. This may also require using a somewhat lower ranking policy that is more effective, or using a combination of policies. This situation is analogous to that faced by a stock market investor who wishes to invest in the stock with the highest rate of return, but who may have to invest in lower return stocks as well if the number of shares of high return stock is limited.

Table 1.3 Results of the Policy Assessment

Rank Order	Overall Rating	Policy Number	Policy Name
1	1.212	R	EPA dissemination of chemical information - test results and/or labeling
2	1.114	EE	Generic PMN for classes of new chemicals
3	1.073	V	Government support to develop new, better test methods
4	1.061	C	Direct cost subsidy for testing/compliance costs of new chemical development via grant mechanism
5	1.003	DD	"Fast track" PMN's for safe and/or major innovations
6	0.902	W	Government support for education and training programs
7	0.817	D	Direct cost subsidy for testing/compliance costs of new chemical development via loan mechanism (or loan guarantees)
8	0.612	F	Indirect cost subsidy for testing and compliance costs via tax mechanism
9	0.562	X	Actions against existing substitutes for new chemicals
10	0.531	S	Chemical technology extension service, including dissemination of information on test and compliance needs
11	0.463	Y	Fixing time periods for regulatory actions
12	0.463	O	Establish government testing for TSCA requirements
13	0.453	FF	Improve EPA staff capability to assess impact of regulatory actions on innovation
14	0.445	AA	Regulatory exemptions for low volume, new chemicals

Table 1.3 continued

Rank Order	Overall Rating	Policy Number	Policy Name
15	0.440	BB	Regulatory exemptions for small firms
16	0.362	P	Sharing of test data with reimbursement
17	0.354	B	Direct cost subsidy for general new chemical development via loan mechanism (or loan guarantee)
18	0.353	Q	Facilitate private sector joint R&D or joint testing
19	0.332	K	Increased capital availability for new chemical development via tax changes or via SEC rules
20	0.316	T	Antitrust action to favor new, small firms in the chemical industry
21	0.288	I	Decreased taxes on sales of new chemicals
22	0.287	U	Tax adjustments to favor small firms or new entrants in the chemical industry
23	0.268	N	Reduce risk from products liability actions by establishing limits on liability
24	0.263	J	Increased capital availability for new chemical development via government supported venture capital company
25	0.239	A	Direct cost subsidy for general new chemical development via grant mechanisms
26	0.225	L	Reduce risk through government financed insurance for regulatory losses
27	0.221	M	Reduce risk through government procurement of new chemicals
28	0.219	Z	Post-market surveillance of PMN's
29	0.208	E	Indirect cost subsidy for chemical innovation generally via tax mechanism

Table 1.3 continued

Rank Order	Overall Rating	Policy Number	Policy Name
30	0.200	H	Strengthened trade secret protection by limitations on EPA authority to release information
31	0.188	G	Increased patent life for new chemicals
32	0.175	CC	Regulatory exemptions for "low-risk" chemicals

TABLE 1.4

Ranks on Individual Criteria For Seven Policies Ranked Highest Overall

Overall Policy Rank	1	2	3	4	5	6	7
Policy Identifier	R	EE	V	C	DD	W	D
Short Policy Name	Information Dissemination	Generic PMN	Better Test Methods Support	Grants for Testing Costs	PMN Fast Track	Education and Training Support	Loans for Testing Costs
Criterion							
Capacity to Countervail	31	3	22	4	15	9	6
Private Costs	24	15	5	22	13	4	28
Public Costs	7	5	12	17	1	19	15
Administrative Feasibility	1	12	3	5	17	6	8
Time to Implement	5	3	13	1	6	19	4
Support TSCA Aims	1	15	3	5	6	4	10
Other Side Effects	1	10	3	5	7	2	8
Effectiveness	16	4	6	3	14	7	5
Political Feasibility	5	4	3	8	6	2	1

1.5 A Comprehensive Program Opportunity

It is suggested that EPA consider a comprehensive program to offset the unnecessarily restrictive impacts of TSCA on technological innovation. The program would include six of the top seven policy options; R, EE, V, DD, W, and either C or D:

1. (R) EPA dissemination of chemical information - test results and/or labeling
2. (EE) Generic PMN for classes of new chemicals
3. (V) Government support to develop new, better test methods
4. (C) Direct cost subsidy for testing/compliance costs of new chemical development via a grant mechanism
5. (DD) "Fast track" PMN's for safe and/or major innovations
6. (W) Government support for education and training programs
7. (D) Direct cost subsidy for testing/compliance costs of new chemical development via a loan mechanism (or loan guarantee)

The top seven policies include policies designed to reduce the costs of new chemical development directly (C and D), to provide more information (R), to improve the technology needed for compliance (V and W), and to modify the administrative procedures for managing PMN's (DD and EE).

It is important to consider more than one policy for a comprehensive program because no single policy is expected to be able to offset all the unnecessarily restrictive impacts of TSCA on innovation. There is no analytic way to determine how much, or how many programs would be sufficient. However, a package of six policy elements, appropriately designed, should go a long way toward offsetting these effects at reasonable cost while supporting TSCA's primary goal of preventing unreasonable risk of injury.

Two of the top seven policies, C and D, would reduce the cost of new chemical development. They are nearly equivalent, with the grant program rating higher in most respects. Either of these policies would be particularly helpful to small firms and new entrants, but there is no reason to include both of them.

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Policies DD and EE are changes in the administration of the regulatory process under current law. They are complementary programs, designed to address somewhat different issues. The generic PMN, policy EE, recognizes that certain classes of chemicals are very similar, and can reasonably be reviewed as a group, perhaps even including contingent clearance of future developments in the class, subject to certain procedural requirements. This option, which is currently under consideration at EPA, would address the problems of highly specialized chemical producers. The "fast track," policy DD, recognizes the additional public interest in the rapid processing of PMN's for safer or major innovations. It addresses all parts of the industry, with a bias toward new products that meet major social needs; i.e., safe substitutes, major innovations, or other criteria.

Policy R, information dissemination, is designed to improve the market demand for safer new chemicals and thereby offset the commerical bias that TSCA creates in favor of chemicals already on the market. It would favor innovative firms throughout the industry and could complement the other policies.

Policies V and W are designed to improve the technology for compliance with TSCA and ultimately to reduce the costs of compliance. Government is already devoting substantial funds to developing new, improved test methods, so option V is essentially already in place. Government support for education and training programs, policy W, could help meet the current high demand for professionals and technicians for industry and for testing laboratories, which would help all segments of the industry.

If six of the policies were adopted, the total budget costs are expected to be in the range of $3 to $30 million per year. A program involving relatively limited commitment to the more costly elements (policies C, D, W, or V) could cost in the neighborhood of $7 million per year, with about $2 million per year for each element. An experimental or trial program could be implemented at less expense and with a lower chance of disrupting the regulatory process. However, it will be difficult to evaluate an experimental program's effectiveness in view of the uncertainty in data on chemical innovation.

1.6 Conclusion

A comprehensive program to offset the unnecessarily restrictive impacts of TSCA on technological innovation need not be very large, expensive, or disruptive. The analysis in this study suggests that very expensive programs such as grants or tax incentives for all chemical innovation in general are neither necessary, nor cost-effective. Furthermore, this analysis has shown that in order to address unnecessarily restrictive impacts of TSCA on technological innovation it is not necessary to consider programs such as regulatory exemptions for new, small volume chemicals, for low-risk chemicals, or for small firms that would seriously compromise EPA's efforts under TSCA to protect human health and the environment from unreasonable risk of injury and disease.

2. THE EFFECTS OF REGULATION ON TECHNOLOGICAL INNOVATION A BACKGROUND REVIEW

It is widely understood that environmental, health, and safety regulations can change the process of technological innovation. Regulation acts to alter the innovative climate both within and outside individual firms. It also acts to change the structure of industries, thereby systematically changing the proclivity and need to innovate in both existing firms and potential new entrants.

Despite the wide agreement that regulation affects technical innovation, there are surprisingly little data on which to form sound opinions about whether the overall effect is positive or negative. (Hill, 1979) There is even less of a basis for understanding how the effects depend on the characteristics of the regulation, the industry, the firm or the technology. (Hill, et al., 1975; Ashford, et al. 1979)

Environmental, health, and safety regulations can affect the development and use of technology in a number of ways. They can:

- require product safety to be demonstrated prior to marketing;
- require product efficacy to be demonstrated prior to marketing;
- require safety to be proved or require the control of product use after products have been marketed;
- require the control of production technology to reduce workplace safety and health risks;
- require effluent, emission or waste control; or
- require safe transportation of hazardous materials.

The Toxic Substances Control Act (TSCA) acts most directly to require product safety to be examined, if not demonstrated, prior to marketing; and it can also act directly to require safety to be demonstrated even after products have been marketed. Less directly, activities under TSCA may trigger regulatory controls in such additional areas as workplace safety and health, environmental quality control, or hazardous materials transportation.

Regulation can affect innovation either for "main business" purposes or for "compliance" purposes. In the former case, regulation affects a traditional, ongoing activity of the firm; in the latter, regulation demands technological changes not previously within the scope of a firm's ordinary activity. This review, focuses on the impacts of regulation on innovation for "main business" purposes, since that is the primary concern of the present study.

This chapter summarizes a framework for understanding the effects of regulation on innovation that has been developed in greater detail elsewhere by Ashford, Heaton, and Priest. (1979) It reviews some of the empirical literature that illustrates the framework, including literature in the related topic of the impacts of the Food, Drug, and Cosmetic Act on pharmaceutical innovation. The chapter closes with some implications for the effects of TSCA on chemical innovation.

2.1 Effects of Regulation on Innovation for Main Business Purposes

2.1.1 Changes in Expected Profitability

Regulation may change the profitability expected from a portfolio of R&D investments by affecting either the expected rate of return or the perceived risk. Profitability may decrease as a result of regulation-induced costs, delays, or uncertainty. As a result, a firm may modify its level of investment in R&D. Its response to the market pull stimulus for innovation will be modified by actual changes in R&D costs. In addition, if R&D is perceived to be less profitable or to be less certain to pay off, investment may be cut back and fewer main business innovations may be produced.

Perhaps the greatest costs imposed by regulation on new products have occurred in the pharmaceutical industry, where testing for both safety and efficacy are required. Schwartzman has cited several studies that indicate an increase of 100-1000% in R&D costs per new chemical entity. (Schwartzman, 1976) These costs are attributed to toxicological testing, premarket testing, and the increased paperwork required by the Food and Drug Administration (FDA) for registration and approval.

Agency actions, other than promulgating individual standards, can change the profitability of investment in innovation in subtle ways. For example, requiring the submission of confidential data may disturb trade secret protection. This may penalize technological innovation because it decreases the legal protection available to new technologies, and may dampen the desire to develop new products or processes, especially if they are not patentable. On the other hand, it must be recognized that some technologies present enough risk to the public that their components must be disclosed. In such cases, whatever dampening effect occurs toward innovation may be justified by the public benefit of disclosure. Moreover, such disclosure is likely to provide an incentive to redirect innovation along competing, but safer, technical lines.

2.1.2 Changes in the Number of Innovations that Fail for Environmental, Health, and Safety Reasons

Otherwise successful innovations may ultimately fail if they are found to pose unacceptable environmental, health, or safety problems. For example, pesticides in use for some time have often been removed from the market for environmental and health reasons.(Wechsler, et al. 1976) Regulation can increase the number of such failures by imposing new requirements on products. Regulation that requires premarket testing can eliminate such failures of fully developed products by catching problems early.

Care must be taken to distinguish observations of decreased innovation during the period of transition to new regulatory demands (when existing, but never-before-scrutinized, products are taken off the market), from an equilibrium or final state (when the developer scrutinizes products more thoroughly for possible problems during the development process). Overall, the change in failure rate is likely to reduce the output of harmful new products.

2.1.3 Changes in Investment Opportunities Due to Increased Environmental, Health, or Safety Risks

The chance that a new product or process might be unable to enter or remain on the market due to the regulation of environmental, health, or safety problems may discourage investment in innovation, especially for products with limited market potential, such as specialty chemicals. Schwartzman suggests that a shift is occurring in the nature of pharmaceutical innovation, with new applications for demonstrably safe technologies being preferred to open-ended searches for new concepts.(Schwartzman, 1976)

In some cases, the lack of defined standards under a regulatory program can deter new investment. For example, the development of new, high-risk, large-scale processes such as shale oil production, may be hindered by the fact that environmental or work-place regulations are undefined. Here, regulations that specify acceptable emission targets are needed to reduce uncertainty.

Regulation undoubtedly changes investment opportunities; however, the ultimate effect is not generalizable across all industries. Industries that historically have been highly innovative may merely shift the type of products developed. On the other hand, noninnovative industries may find themselves competing with more innovative new entrants.

2.1.4 Diversion of Managerial Personnel

To the degree that important advances in marketing, financing, strategic planning, and corporate organization depend on actions by management, the diversion of management to regulatory tasks can have serious implications for the innovative performance of firms. It is important to distinquish between transition diversion and administrative diversion. Transition diversion occurs as the emergent regulations create new problems with which management must deal. Once management has decided on a strategy to address these problems, the transition diversion will disappear. What remains is a need to monitor the compliance efforts and the regulatory developments that are likely to follow. This administrative diversion will accompany management as long as the problems to which regulation is addressed remain. Much of the literature about the diversion of management is addressed to the transition problem, rather than to the long-run effects of regulation on management.

2.1.5 Diversion of R&D Resources

Regulation causes some firms to redirect resources away from conventional innovative activities into compliance-related activities, which will tend to reduce main business innovation. If, as some say, the long-term marginal rates of return on R&D investment are as high as 30-50 percent, (Mansfield, 1976) this highly productive use of resources is not likely to be significantly reduced by firms. Instead, other ways to reduce spending will be found, and the opportunity cost of regulation will be more likely reflected in a cutback in outlays for expansion and acquisition than in outlays for R&D. Moreover, early scrutiny of the environmental effects of new technologies can offset much of the diversionary impact on R&D. For example, Mansfield points out that in the chemical industry, 83 percent of the costs of new product development occur after the applied research stage and 57 percent occur after the pilot plant stage. (Mansfield, et al., 1971) This finding implies that earlier rejection of potential new products would be less costly than rejection nearer to commercialization.

When R&D resources are diverted as a result of regulation, it does not follow that there is a corresponding proportional decrease in total innovative output. In small firms, incremental reductions in R&D could have significant results, especially if they have limited access to capital. On the other hand, such incremental decreases may not lead to particularly dramatic results in large firms, which may already have surpassed the advantages of economies of scale in R&D.(Schmookler, 1972)

Innovation in large firms may even increase if organizational red tape and communication barriers decrease with personnel reallocation. The productivity of R&D for innovation may be improved in other ways if regulation encourages the more efficient use of resources. In sum the effect of resource diversion on innovation is not well-established.

2.1.6 Ancillary Innovation from Redirected R&D

Redirection of R&D may result in more innovation. A study of governmental effects on the innovation process in five foreign countries found that innovations for ordinary business purposes (not necessarily for compliance) were much more likely to be commercially successful when environmental, health, and safety regulations were present as an element in the planning process than when they were absent.(CPA, 1975) In addition, compliance-related technological changes often led to product improvements far beyond the scope of the compliance effort. In an example from the five-country study, a textile manufacturer developed a new dye in order to minimize worker exposure to toxic fumes. In so doing, he arrived at a dye which was also more colorfast and, hence, a better, more saleable product.

Ancillary innovations often appear to be the unexpected or serendipitous results of regulatory compliance efforts, which may occur because of the necessity (brought on by regulation) to rethink established and previously unquestioned modes of operation.(Allen, et al. 1978) There are enough of such innovations, however, to suggest that they may be predictable phenomena.

2.1.7 Regulation-Induced R&D and Process Improvement

Regulation creates opportunities for firms to make process improvements unrelated to compliance. These appear to occur more frequently as a greater technological change is required to comply. Two examples from a study of chemical innovation illustrate the pattern.(Ashford, et al., 1979) In one instance, the petroleum refinery industry developed improved catalysts, and, consequently, a more efficient system, as a result of the R&D that went into the effort to comply with regulations to control lead in gasoline. Similarly, the need to limit employee exposure to vinyl chloride monomer led to the creation of a more efficient production system and to some increase in output.

Similar phenomena have been uncovered in other studies. Iverstine reported that 33 percent of his study's respondents cited process improvements resulting from regulatory changes; these included the development of closed systems and better process instrumentation. (Iverstine, et al., 1978) The Denver Research Institute similarly found that regulation provides an opportunity to make process improvements in areas not related to regulation.(Boucher, 1976)

Because it is less expensive and disruptive to make multiple changes simultaneously, businessmen naturally take the opportunity of regulation to introduce other improvements. Such improvements are often complementary to the regulatory purpose (e.g., safer closed systems with greater yields). They may often be suggested by the R&D that was necessitated by regulation. Although these improvements might have occurred eventually, regulation can be viewed as accelerating normal business innovation.

2.1.8 Rechanneling Creativity

The innovative potential of a firm is, in large part, a function of the creative energies and abilities of its personnel. While one effect of regulation is to divert personnel from the normal business of the company to regulatory problems, there also appears to be an opposite effect - the creative potential of the firm is rechannelled, augmented, or enhanced.

Because compliance involves a large component of technical expertise, many of the people brought into firms to assist in compliance are highly trained professionals--typically, environmental scientists or engineers When this new source of expertise enters the normal R&D process, innovative products and processes are likely to result. Some of the companies interviewed in the study of chemical innovation by Ashford, et al., (1979) mentioned the recent need for sophisticated analytical chemistry expertise in order to assess the health and environmental risks of both new and existing products. They felt that the sophisticated analyses gave the companies a better knowledge of the properties of their products and suggested new uses for them. They believed that this new analytical capability would be important in developing new products and processes. The same phenomenon was noted by 33 percent of the interviewees in Iverstine's study.(Iverstine, et al., 1978)

An explanation for increased creativity under regulatory conditions was offered by Allen and colleagues, (1978) who argued that regulation, besides adding new dimensions to older problems, "increases the problem space of the engineer." The need to optimize along several new dimensions is likely to foster more creative solutions than those that prevailed under less complex conditions. This effect is especially likely to occur in older, more rigid, industries where few external stimuli have demanded creative responses.

2.1.9 Change in Industry Structure

Regulation may have different impacts on firms within an industry and may change the composition of that industry. The mix of size of firms or the competitive environment may change. The structural alterations brought about by regulation will in turn affect innovation. Regulation influences the quality and quantity of innovation insofar as it changes barriers to the entry of new firms into an industry, the balance of firm size, and the extent of monopoly power. Distinguishing between the effects of regulation and of other influences (e.g., changing technology, or inflation) is a difficult methodological problem, and no consensus has emerged as to the relative importance of these factors.

Barriers to the entry of new firms into an industry are introduced when compliance measures are expensive and subject to economies of scale.(Leone, 1977) This may be offset to some extent if new entrants are able to meet regulatory requirements at lower costs, since they do not have to engage in costly retrofit activites. Regulation can create market opportunities that attract new entrants, especially those with a new technology. For example, there are now several competing substitutes for PCBs; whereas, before the regulatory ban, there was only one manufacturer and no accepted substitutes in major applications. (Ashford, et al., 1979) In general, regulation is likely to make it somewhat harder for firms and industries to compete and survive in a more dynamic market.

There is general agreement that small firms are harder hit by regulation, although the evidence is primarily qualitative.(Iverstine, et al., 1978, Boucher, et al., 1976) The effects of resource diversion mentioned earlier may fall more heavily on the small firm due to its limited resources. Regulatory agencies tend to concentrate their enforcement efforts on the larger firms. However, small firms are limited in their ability to influence policy, and regulations are not typically designed with their special problems in mind.(Charleswater Associates, 1975) Some regulatory agencies now have programs directed at the needs of small firms.

Innovation may decrease as a result of increased entry barriers and decreased competition caused by regulation. The effect will be reduced if regulations contain provisions, say, for variances of financial assistance for small firms. There may be a compensating effect, however, since regulation provides new market opportunites for new entrants, especially those with new technologies. Existing firms may try harder to retain their market share through innovative competition. These long-term effects may have the most important influence on innovation. (Eads, 1979) Quantification of the net effects is speculative due to the presence of additional influences, the diversity of industry structures, and the lack of suitable aggregate measures of innovation that capture both quantity and quality differences.

2.2 Effects of Regulation on Compliance Innovation

Regulation clearly encourages technological changes for compliance purposes. However, such changes will not necessarily be innovative. Regulatory mandates often elicit the adoption of technologies that are fully developed, but on the shelf. Moreover, in cases where the regulatory standard is set at the level of the best practice in a few leading firms, the major effect that occurs is diffusion of an existing technology to the lagging firms--a noninnovative, although important, response.

It is in the best interest of both firms and society to encourage the development of innovative compliance technology. To the firm, such technology is likely to reduce the cost of meeting regulatory goals. To society, the adoption of better, safer technologies resulting from innovation is an important addition to the benefits of regulation. Moreover, to the extent that the overall impact of regulation is to demand a long-term and widespread alteration in the nature of industrial technology, innovation is crucial.

2.2.1 Redirection of Technological Capabilities for Environmental, Health, and Safety Purposes Only

Most compliance technologies adopted by a sample of 50 chemical firms in a study by Ashford, et al.(1979) were found to be in a late stage of development when the regulatory signal was acted upon by the firm to meet regulatory demands. Similarly, the great majority of responses were based on well-established technologies. Responses involving modifications of an industrial process as opposed to a product tended to be more comprehensive in scope; there were, however, significant exceptions.

2.2.2 Saleable Compliance Technologies

The great majority of compliance technologies are developed in the firms that are directly subject to regulatory requirement.(Iverstine, et al., 1978, Boucher, et al., 1976) However, there is also a large market for the sale of goods and services to meet compliance requirements. Some of these sales are made by regulated firms seeking to market the technologies developed to solve their own in-house control problems. Although it is not clear from the existing research whether recognition of sales potential most often predates the development of compliance technology, or is actually an after-the-fact appreciation of market potential, the attempt to sell compliance technologies appears to be fairly common. Most often, the sales are to other firms in the same industry. One study showed that a developer of a less-polluting process for the production of chlorine tried to market it to other firms in the chloralkali industry. Iverstine's study documented that a large percentage of firms were able to sell the pollution control technology they had developed.(Allen, et al., 1978) On the other hand, the study also indicated that the uniqueness of each firm's environmental, health, and safety problems often makes such sales difficult.

The need to create new compliance technologies, and the dynamic relationships between the regulated and pollution control industries, have restructured the innovative effort in many industries. For example, the regulations to control lead in gasoline appear to have encouraged diversification among lead additive manufacturers, including the development of some highly innovative new automotive technologies.(Ashford, et al., 1979) Similarly, the suppliers of automobile parts, perhaps more than the automobile manufacturers, have been a major responder to regulatory demand, thereby changing the balance of innovative activity within the industry.(Rubenstein and Ettlie, 1977)

2.2.3 Compliance Technologies with Ancillary Benefits

Technological change to comply with regulation can provide ancillary benefits to the complying firm. These benefits are more likely when compliance responses are innovative and/or comprehensive in scope.(Ashford, et al., 1979)

Typically, ancillary benefits result from the ability of the firm to transfer the technologies developed for compliance purposes to other uses. For example, the use of microprocessors in automobiles to regulate fuel consumption and emissions has opened the door to other applications of this technology for improving performance.

From the point of view of the firm, the ancillary benefits of regulation may result from serendipitous, unpredictable events. However, the documentation of such effects in several studies leads to the conclusion that this phenomenon is, on the whole, to be expected.

2.2.4 Joint R&D Efforts for Compliance

Firms within an industry often share the results of their research on compliance methods--especially with respect to difficult regulatory problems--even when they do not undertake it jointly. One study found such sharing in 53 percent of its sample.(Iverstine, et al., 1978) Although this phenomenon is not likely to have a major impact on the development of new compliance technologies, it may have an important impact on the diffusion of appropriate solutions.

2.2.5 Reorganization of Firms to Meet Compliance Requirements

It has been widely reported that regulation has fostered organizational change in companies. A study of innovation in the chemical industry found that about 65 percent of the chemical firms interviewed had formal environmental affairs groups (Ashford, et al., 1979) and the Conference Board recently reported that 78 percent of a sample of chemical and pharmaceutical firms have government relations units.(C&E News, 1979) These groups often serve primarily as a liaison between the regulators and their company. They participate regularly in the regulatory process, often indicating to the regulatory agencies the technical limits of existing compliance capability.

This interaction is seen by some as a way of tempering potentially strict technology-forcing regulatory standards by considerations of "feasibility," and also as a way by which the holders of certain compliance technologies can "capture" the regulatory standard for their particular compliance method. (Eads, 1979) The environment affairs unit often functions within the firm in a manner very similar to a regulatory agency. Environmental review procedures are frequently established, with the environmental affairs unit able to "pass" on the acceptability of various products or processes, particularly in their early stages of development. Thus, these groups will encourage the development of safer technologies.

Environmental affairs units are more common in large than in small corporations. They are typically located in the central corporate headquarters, rather than in production facilities. They may be staffed with young environmental scientists rather than engineers. As such, it appears they often do not play a major role in the development of new compliance technology or in the engineering aspects of compliance. These functions are more typically within the realm of the engineers at the plant level, or R&D personnel.(Ashford, et al., 1979)

2.2.6 Information Sources for Compliance Technology

One barrier to effective regulatory compliance is a lack of knowledge about the best technical solutions, especially in smaller firms. Government agencies such as Occupational Safety and Health Administration (OSHA) have programs to assist firms in developing appropriate compliance responses. In fact, the OSHAct mandates a program of assistance for small business.

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The efficacy of information programs sponsored by the government is open to some question. One study reported that less than one percent of all solutions to environmental problems originated with the government.(Iverstine, et al., 1978) Another study reported a widespread perception that EPA is deterred from establishing closer working relationships with industry for fear of legal or political reaction by environmental groups. (Boucher, et al., 1976)

In addition to government action, a firm's personnel assigned to the regulatory compliance function plays an important informational role.(Boucher, et al., 1976) In the regulatory area, these individuals provide liaison between the firm and outside technical knowledge, which can be a force for innovation in both compliance and noncompliance areas.

2.3 Effects of the Kefauver-Harris Amendments on Drug Innovation

The impacts of the 1962 Kefauver-Harris amendments to the Food, Drug, and Cosmetic Act on drug innovation have been widely studied, and they may provide some insight into the effects of TSCA on chemical innovation. Of course, there is no doubt that TSCA is a different type of regulation with some qualitatively and major quantitatively different barriers to innovation. Therefore, the analogy to drugs, while useful, is not an exact replication of the chemical industry. This discussion focuses on changes in corporate strategy and on industry in response to the new regulations.

In the drug industry, Jadlow (1976) found that "the rate of innovation was greatest in the period 1955-1960 in those drug markets where small firms were introducing new products and taking market shares away from the largest sellers." He showed that the smaller firms in the actively innovating market segments played a significant role prior to the 1962 drug amendments. In the period 1963-1972 he showed that the large firms were able to obtain economies of scale in research. These economies of scale, along with regulatory barriers and the large capital requirements to buy into research, constituted major disincentives for new, small firms to consider entry into the industry.

Jadlow attributed some of the economies of scale in research to advantages in meeting compliance requirements. He concluded that: 1) any policy that reduces seller concentration decreases innovation, and 2) it is desirable to reduce cost disadvantages to small firms in order to increase innovation.

Today the drug industry still contains many small firms, but according to Schwartzman (1976), it appears that large firms devote proportionately more effort to R&D and produce more products than small firms. Their role apparently has changed since the 50's when small firms accounted for a large percentage of product innovation.

Randall (1972) carried out a series of interviews with drug firms that resulted in an understanding of the strategies that firms had adopted in response to regulation:

- continue "in an already established line of research mode", use new technology to increase the sophistication of the research effort and concentrate efforts on long range breakthrough products."
- continue in special areas where the firm had demonstrated high innovation capability. Extend research efforts in technologically related product areas in order to ease the burdens of long periods without breakthrough products.
- concentrate in short run, developmental areas, acquire products from other firms in an effort to improve a product line rapidly.

These strategies were adopted by those companies still devoted to R&D. Other companies ceased doing R&D and went into the production of generic products; that is, products on which patents have expired and that are produced by other manufacturers. Generic drugs offer the potential for market penetration and survival for small firms through cost advantages and lower prices. Sales advantages can be obtained through undercutting the pricing policies of the firm that developed the product. The firms that develop the drug set prices to cover a substantial portion of their total R&D; they take advantage of the monopoly position offered by the patent system by setting a high price. In the chemical industry, product turnover is more rapid than in pharmaceuticals, substitutes are more readily available, and the largest firms dominate the production process, so that the generic product strategy used by small drug firms may not offer survival to the smaller chemical companies.

Most researchers attribute the changes in the market structure of the drug industry to the imposition of the 1962 Drug Amendments. There is little question that the regulations encouraged such changes, however, several other changes in the nature of the industry were underway before the 1962 amendments.

One of these changes was the type of discovery process used in the industry. Discovery shifted from molecular modification and screening to a more rational process, that requires more intensive research efforts (Ashford, Butler and Zolt, 1977; Hattis, et al., 1980). At the same time, competition from around the world was increasing, putting particular pressure on small firms. A final argument often presented is that the drug industry goes through cyclical perids of discovery and fast growth followed by consolidation and slower growth. The 50's are characterized as a period of rapid growth in which the technical capabilities of the industry combined with basic research to produce new products. The interim period, the 60's and 70's, was a time of consolidation, process change and reinvestment in basic science.(Ashford, Butler and Zolt, 1977) The 80's appear to be offering another turn of the cycle that will return this industry to the dynamic growth experienced in the 50's. The evidence for this comes from a recent upturn in drug product submissions, and very optimistic remarks by leaders in the drug industry.(Bloom, 1978)

Following passage of the Kefauver-Harris amendments in 1962, small firms in the drug industry were acquired by other firms, dropped out, produced generics, or specialized in a market niche in which they had strength. The precise strategy used depended on the company's market position, anticipated market position, and internal technical skill. In the chemical industry, TSCA is not expected to impose as dramatic an entry and survival barrier as the 1962 amendments did for drugs.

2.4 Implications for the Probable Impacts of TSCA on Technological Innovation

TSCA is a major new regulatory stimulus that may have significant, but currently uncertain impacts on technological innovation in the chemical and related industries. At minimum, the procedural requirements of TSCA's pre-manufacturing notification system will introduce some additional delays and costs in the process of innovation. For a portion of both new and existing chemicals, TSCA may lead to additional costs and delays to meet requirements for additional testing, or it may even lead to more restrictive actions such as limitations or prohibitions on the manufacture and use of chemicals.

As a product regulation, TSCA can be expected to have its primary effect on product innovation. However, because TSCA can also lead to controls on manufacture and use practices, and because product and process innovation are often intimately intertwined, TSCA may affect process and systems innovation as well.

TSCA may not be limited to inhibitory effects on product and process innovation. Experience with pre-market product regulation in the pharmaceutical industry and with effluent regulation in the chemical industry shows that regulation can sometimes accelerate or even stimulate technological innovation. These effects are seen not only for technologies required to comply with regulation, but also for technologies not directly related to compliance.

The evidence presented in this chapter and in Appendix B suggests that TSCA may seriously affect the ability to innovate of small firms, of new entrants, or of firms whose products are inherently sold in small volume. This effect may be especially severe during the period of transition from the pre-TSCA to post-TSCA state. Furthermore, the unequal treatment of existing and new chemicals under the Act may also inhibit innovation in these cases.

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3. A FRAMEWORK FOR ASSESSING THE EFFECTS OF TSCA ON CHEMICAL INNOVATION

3.1 Legislative Background

The fundamental purpose of the Toxic Substances Control Act (TSCA) is to prevent chemicals from presenting an unreasonable risk of injury to health and the environment. The Act gives the Environmental Protection Agency a variety of authorities to require testing of both existing and new chemicals, to require notification before new chemicals are manufactured or before chemicals are used in significant new uses, and to regulate the production, use, and disposal of chemicals that are found to pose an unreasonable risk.

The implementation of TSCA by EPA can be expected to modify the constraints and opportunities under which both new and existing chemicals are developed, marketed, or used. Thus, TSCA can be expected to affect the economic performance of the chemical industry in such areas as profitability, growth, imports, exports, employment, and technological innovation. The model and literature reviewed in chapter 2 of this study make it clear that regulatory programs analogous to TSCA have had a variety of impacts on economic performance and especially on innovation. This review also makes it clear that regulation can enhance, inhibit, or redirect technological innovation, depending on the exact form of the regulatory requirement and the nature and stage of development of the industry and its products and process.

Congress was mindful that TSCA might affect the economic performance of the chemical industry and that technological innovation could be especially affected. Thus, in the statement of policy in Section 2(b)(3) Congress said:

> Authority over chemical substances and mixtures should be exercised in such a manner as not to impede unduly or create unnecessary economic barriers to technological innovation while fulfilling the primary purpose of the Act to assure that such innovation and commerce in such chemical substances and mixtures do not present an unreasonable risk of injury to health or the environment.(emphasis added)

This section of TSCA makes it clear that Congress fully anticipated that implementation of TSCA might "impede...or...create...economic barriers to technological innovation" as the Agency carried out its primary purpose "to assure that...chemical substances do not present an unreasonable risk." Thus, the framers of the Act expected some negative effects on innovation and directed the Agency to take care not to inhibit innovation any more than necessary to carry out its primary regulatory charge.*

3.2 Administrative Discretion

Under TSCA, the EPA Administrator has considerable administrative discretion over which chemical substances to regulate and over the detailed design and implementation of the procedural and regulatory authorities he is to exert. He also has authority to provide various kinds of technological and administrative assistance to regulated parties. Within the scope and range of this discretion the Administrator could have significantly different effects on innovation while regulating effectively.**

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*That TSCA may also stimulate technological innovation in certain sectors of the industry and especially of safer chemicals than those now in use is not addressed explicitly in the Act but is also of concern, as discussed in Section 3.3

**Many of the rules and procedures to implement TSCA are being developed by EPA at the present time, and Section 2(b)(3) is one consideration that guides EPA in this work. To provide a reasonable basis for comparison of a wide variety of policy options, we have included among the options assessed in this study several actions which EPA has, or intends to implement. As a result, this report tends to overstate the potential restriction of innovation by TSCA regulation.

In addition to addressing the innovation problem directly by careful design of its regulatory programs under TSCA, EPA could consider two other routes to execute its charge to be concerned for chemical innovation. It could encourage other agencies of government to pay special attention to the needs of the chemical industry, such as research and education authorities (e.g., National Science Foundation or National Institutes of Health) or economic development authorities (the Small Business Administration, the Economic Development Administration, or the Patent Office). As a third approach, EPA could seek additional authorization from Congress to address innovation directly through, for example, authorization to offer financial assistance to firms for innovative activities or for regulatory compliance. All three of these approaches are considered in this study.

3.3 Understanding the Issue: A Framework

If EPA is to take actions so as not to unduly impede or create unnecessary economic barriers to technological innovation, there is a need to understand how and where such undesirable effects might arise and what forms they might take. Only then can sensible policy options be designed and assessed.

This report is devoted to the design, assessment and analysis of cost-effective policy options that could offset the unnecessarily restrictive effects of TSCA on technological innovation while not jeopardizing fulfillment of the primary purpose of TSCA. The policy options are designed to be responsive to the following considerations.

i) Projections of the future course of technological innovation in the chemical industry are highly uncertain, even without TSCA

It is useful to think of technological innovation as a process whose outcomes are new, commercially successful products, processes, systems or services. The process involves inputs of human and financial resources to such activities as research, invention, development, testing, marketing and diffusion.

Appendix B discusses the process and outcomes of technological innovation in the chemical industry in some detail. There it is noted that a variety of factors in the scientific, financial and competitive environment of the chemical industry are changing and that even in the absence of TSCA, historic trends in chemical innovation are unlikely to be followed in the future. Contributing to this is the fact that developments in products liability and environmental and occupational regulation are influencing chemical innovation quite apart from TSCA's effects. It is also pointed out in Appendix B that there is not yet a good understanding of the nature and sources of chemical innovation. For example, there are no sound data on the number of new chemicals marketed each year, or on the contributions of small and large firms or new entrants to chemical innovation. A few studies have found that large firms are more innovative than small ones, but even these results are open to serious question.

Since TSCA is primarily concerned with regulating products, it is reasonable to focus our attention, though not entirely, on product innovation. Figure 3-1 illustrates the difficulties in projecting chemical product innovation, even if TSCA had not been passed. Data on past chemical innovation are not available. For the future, a wide range of possibilities exist, depending on which of the current forces dominate. Furthermore, in the absence of TSCA, the concern for safety might decelerate innovation if it causes producers to be less aggressive in marketing new products, or it might accelerate innovation if consumer demand causes a shift to new safer products as substitutes for old ones.

ii) TSCA may stimulate, inhibit, or redirect technological innovation, or it may do all three simultaneously

Superimposed on the uncertain future of chemical innovation are the variety of effects that the TSCA regulatory requirements may have.* As

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*Regulation in this context includes both the procedural requirements such as premanufacturing notification and substantive requirements such as use restrictions or testing requirements.

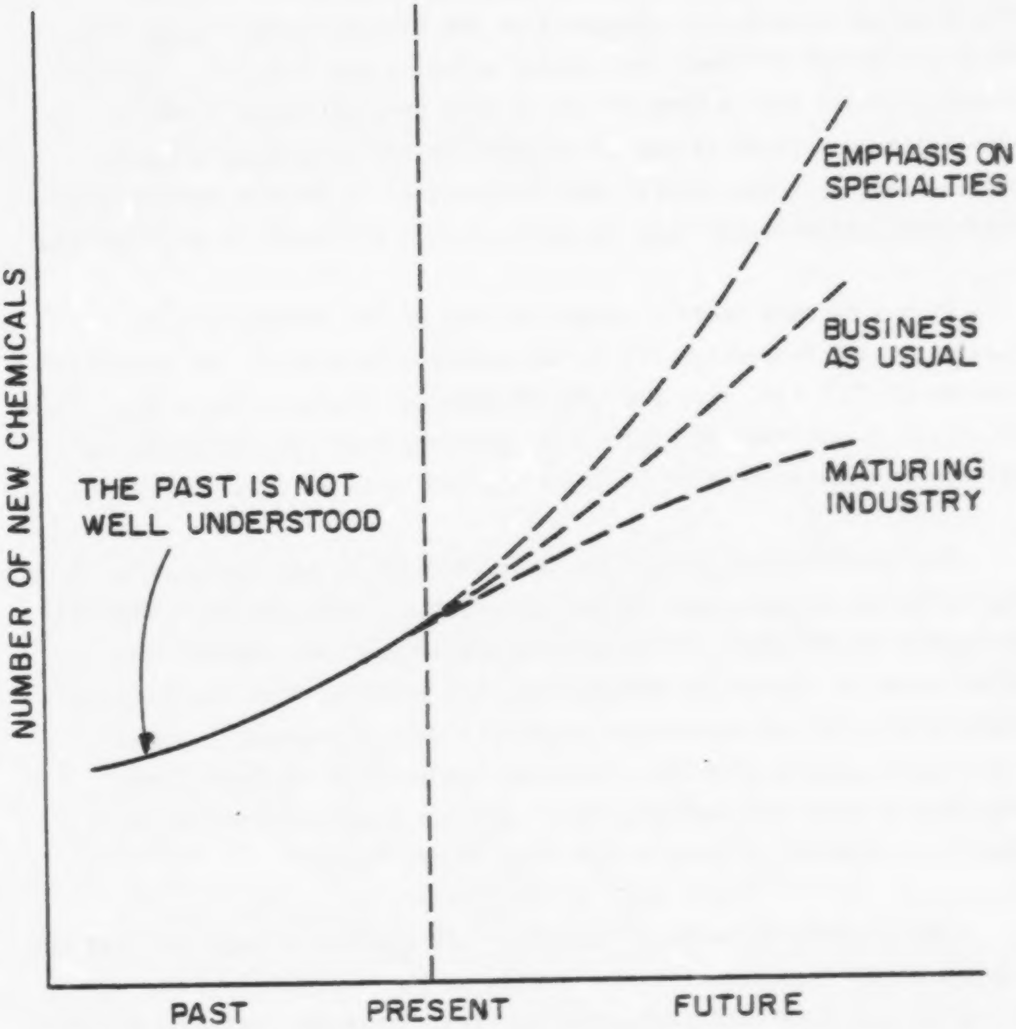

FIGURE 3.1 SOME SCENARIOS FOR THE FUTURE COURSE OF CHEMICAL INNOVATION IF TSCA HAD NOT BEEN PASSED

noted in chapter 2, environmental, health, and safety regulation can act through a variety of mechanisms to inhibit, stimulate or redirect technological innovation, depending on the circumstances. Since TSCA features several different regulatory stimuli, and since the "chemical industry" is in fact a combination of many very different kinds of industries in various stages of maturity or rigidity whose products differ greatly in the hazards they present; it is to be expected that inhibition, stimulation, and redirection will all occur at the same time.

At our current level of understanding of the interaction of regulation and innovation, it is not possible to predict the quantitative outcome of TSCA for, say, the rate of chemical product innovation. This situation is outlined in Figure 3.2, assuming that innovation in the absence of TSCA would have followed the "business as usual" scenario.

The inhibition of innovation by TSCA would arise, for example, from the marketing delays, testing costs, resource diversion, and commercial uncertainties it would introduce into the innovation process. The stimulation of innovation would arise, for example, from the increased staff diversity and rejuvenated corporate decision-making process required to comply with TSCA. Redirection would arise from firms electing to seek safe substitutes or abandon lines of research into chemicals expected to pose a high risk to health.

The research reviewed in chapter 2 and appendix B suggests that the inhibition of innovation is more likely to occur in small firms, new entrants, and makers of innovative specialty products, while stimulation is more likely to occur in large, established, mature firms that use highly-integrated process technology. At the same time, regulation can also stimulate innovation in some small firms and new entrants and inhibit it in some mature firms. Thus, redirection due to TSCA can occur in both the nature and sources of chemical innovation.

iii) Some degree of inhibition of technological innovation was anticipated in TSCA and is of no concern of EPA.

Historically, some of the new products and processes manufactured or used by the chemical industry and its customers have posed unreasonble

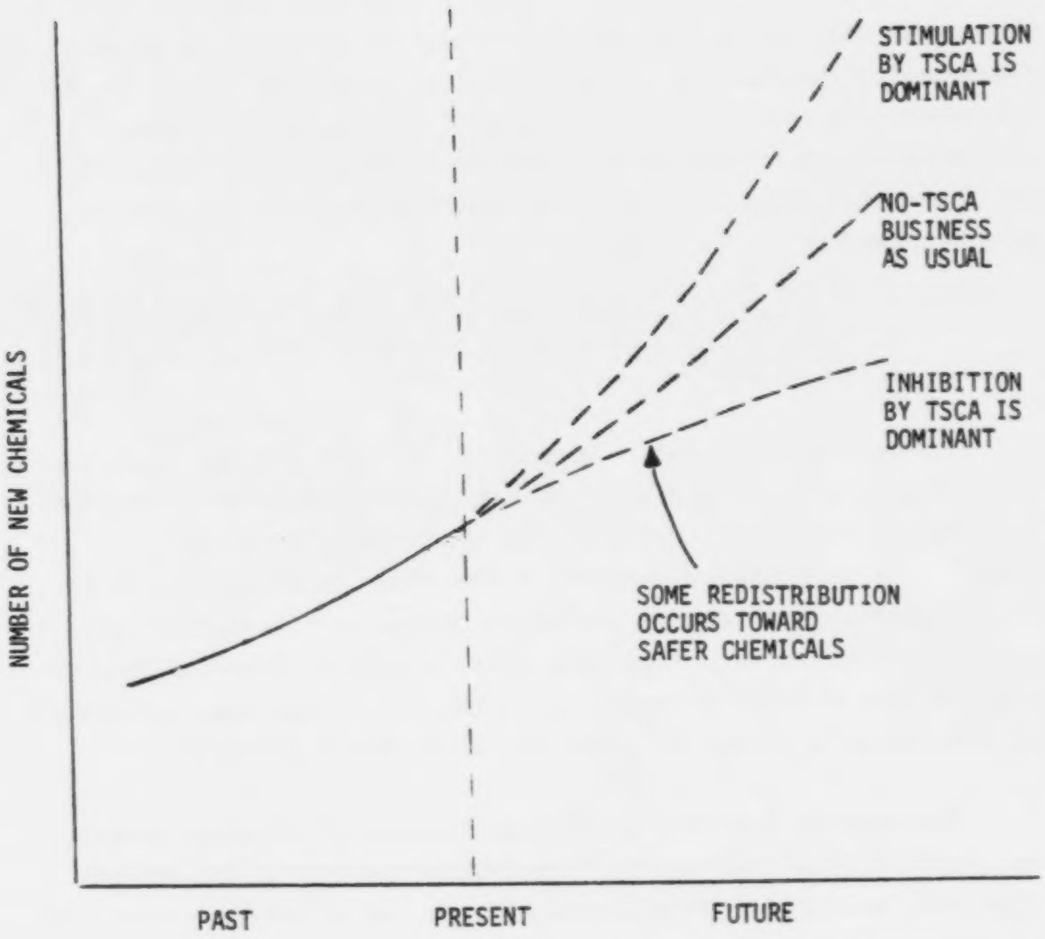

FIGURE 3.2 SOME SCENARIOS FOR THE COURSE OF FUTURE INNOVATION WITH TSCA IN PLACE (COMPARED WITH THE NO-TSCA BUSINESS AS USUAL SCENARIO)

risks of injury to health and the environment. One of the main purposes of TSCA is to slow the rate of introduction and/or encourage the more prudent use and operation of such products and processes. Thus, some inhibition and some re-direction of chemical innovation was expected due to TSCA - it was part of the social bargain struck by Congress. Thus, an observation that the rate of chemical innovation has declined, or that the nature of chemical innovation has shifted is not, by itself, grounds for determining that EPA has acted "unduly" or "created unnecessary economic barriers to innovation." Therefore, offsetting policies should not attempt to return the rate and direction of chemical innovation to some hypothetical pre-TSCA baseline.

iv) It is not possible to know from examining the historical record or from projections about the future whether the observed rate of technological innovation is that which Congress intended to result from TSCA.

As discussed in chapter 2, appendix B, and this chapter, there are great uncertainties in both the historical record and future projections for chemical innovation. There are not models which allow for quantitative projection of the rate of innovation in an industry or for the influence of such complex regulatory schemes as TSCA on that rate. Thus, if in the future an interested party alleges to EPA or to Congress that the rate of chemical innovation is too low, or too high, as a result of TSCA, there is no way to support or refute such a statement.

This does not mean that sensible actions cannot be taken, however. Analysts can argue from empirical observation and on *a priori* grounds about the impacts of different regulatory options or offsetting policies on the process on innovation, and from these arguments can make informed judgments about the relative effects and effectiveness of various approaches. This is done in chapter 5 of this report.

v) The implementation of TSCA may have some unnecessarily restrictive effects on technological innovation.

Earlier, it was asserted that TSCA will inhibit chemical innovation to some degree and that some part of that inhibition was intended by Congress. Similarly, it can be asserted that the implementation of TSCA may unnecessarily restrict technological innovation despite EPA's best intentions. However, because of the great uncertainties about the innovation process, it is not possible, or necessary, to attempt to draw a clear distinction between the justifiable and the unnecessarily restrictive impacts of TSCA.

3.4 The Origins of Unnecessarily Restrictive Impacts on Innovation

Two concepts, regulatory fine tuning and transition phenomena, help explain the origins of the unnecessarily restrictive impacts of TSCA on chemical innovation.

First, consider "regulatory fine tuning." TSCA gives the Administrator of EPA considerable discretion in carrying out the main purpose of the Act: to prevent unreasonble risk of injury due to chemicals. Yet, despite the many special provisions and wide latitude for decision making embodied in the Act, rules to implement TSCA are likely to bear more heavily on some parties than on others in ways which are unnecessary to accomplish the regulatory goals. This is likely to happen as a result of the need to compromise fine tuning of the rules and procedures for political and administrative feasibility. On the other hand, the very complexity of TSCA may cause unnecessary burdens for some regulated parties, such as costs, delays or uncertainties, that would unnecessarily restrict innovation.

Consider next, "transition phenomena." When a new law is passed that is intended to influence industrial behavior, a finite period of time elapses while the rules and procedures to implement the law are adopted. During this period, firms and investors may perceive a high level of uncertainty in making business decisions. Also, for a time after the law is passed and implemented, the infrastructure necessary to respond to the law's requirements may not be in place. For example, trained people and facilities required to do tests to comply with TSCA's rules may not be available at reasonable cost, if at all, for several years. During the period, newly-regulated firms can be seriously disrupted, and smaller firms may even disappear with the result that innovation declines, even for safer chemicals.

Congress and the agency do not intend to burden industry with these transition phenomena or to use rules and procedures that are inadequately tuned to the needs of industry, yet some problems are inevitable if a vigorous new regulatory program is to be put in place to accomplish the primary goal of controlling unreasonable risk. To the extent that the regulations unduly inhibit or create unnecessary barriers to technological innovation, and to the extent that these undesirable effects can be corrected by policies whose costs are commensurate with the benefits they offer, EPA and/or Congress may wish to take action to put such policies into action.

3.5 Small Firms, Small Volume Chemicals, and New Entrants

Small firms, especially those that specialize in new products, may be especially burdened by transition phenomena, as well as by problems arising from the insufficient degree of fine tuning in, or complexity of, TSCA. Similarly, new chemicals that will only be produced in small amounts (a condition that can often be judged before marketing with fair certainty) will also be heavily burdened by TSCA's requirements.

For example, large firms that sell many products can achieve economies of scale in administrative costs of regulatory compliance, and, inevitably, can receive more attention to their needs from regulators than small firms. Chemicals produced in small volume may have to bear the same costs of PMN submission and/or testing as larger volume ones (although EPA's priority setting may consider production volume as a factor in deciding to require testing), which may put them at an economic disadvantage. Or, firms entering the chemical industry for the first time with a new product may experience extraordinarily high costs of learning how TSCA programs work. As discussed in detail in appendix A, the seriousness of these problems for the firm depends heavily on the detailed circumstances of supply and demand for the product, for its substitutes, and for inputs to its production. Ideally, the regulatory effort should be tailored to every such circumstance. One way to attempt such tailoring is to adopt policies that offset the unnecessarily restrictive impacts arising from the degree of regulatory fine tuning and from transition phenomena.

3.6 The Stimulation of Safer New Products and Processes

Parallel to the concern for the unnecessarily restrictive impacts on technological innovation is the interest in the development of safer chemical products and processes. The innovation of safer substitutes is a socially desirable outcome that the unregulated market will not produce in sufficient numbers; a major reason for TSCA's existence.

As noted in the welfare economic discussion in Appendix A, government intervention to increase the production of safe chemicals is a separate policy issue from the concern for the possible unnecessarily restrictive impacts of TSCA. However, the two concerns are related, since the impacts on innovation could include a reduction in innovation of safer products and processes. It is likely that programs intended to offset unnecessarily restrictive impacts of TSCA on innovation could also be designed to enhance the innovation of safe substitutes. This possibility is included in the assessment of policy options in chapter 6.

3.7 Conclusion

For largely unavoidable reasons, TSCA and its implementation may unnecessarily restrict technological innovation in the chemical and related industries. It is not possible to quantify the extent of this restriction, or even to know whether the net effect of TSCA on chemical innovation will be expansive or reducing. In fact, some degree of inhibition of innovation is intended by TSCA. However, our understanding of the innovation process and of the inevitable compromises and simplifications inherent in the regulatory process lead to the above conclusion.

Where actions might be taken by EPA, by other agencies, or by the Congress to offset these unnecessarily restrictive effects on innovation without compromising the primary goal of TSCA, and where such actions can be taken at a cost lower than the costs they create, such actions would be fully in harmony with Section 2(b)(3) of TSCA. The next chapters design and evaluate some thirty-two separate actions that might be considered.

4. POLICY OPTIONS FOR CONSIDERATION

4.1 Developing Policy Options

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A major task in this project was to develop a list of possible policy options for eliminating or mitigating the potential effects of TSCA on technological innovation. This list of options is intended to be widely representative of the possibilities for government action and to reflect the wide variety of policy options that have been proposed by various parties. Some of the options could be implemented administratively; others would clearly require new legislation. Both are potentially important approaches to encouraging innovation.

The list is comprised of policy options to encourage innovation. These proposed policies are directed at only one of the many legislative goals of TSCA - not to unnecessarily restict technological innovation. They are not strategies for the implementation of TSCA, but are intended as only a part of such a strategy. The policy list was developed with innovation foremost in mind. Thus, it may contain options that should be rejected because they are inconsistent with TSCA's other goals, as reflected in the evaluation of the policies in chapters 6 and 8.

The generation of the list began with an analysis of the process of technological innovation described in chapter 2 - what drives it, what impedes it, and how it progresses. It was then possible to develop a construct of the barriers and incentives to innovation that government can influence. For example, it can alleviate shortages of capital for new investments (a barrier) or guarantee markets (an incentive), but cannot affect management creativity to any great extent.

Based on the construct, we developed a series of programs that government can use to encourage innovation by overcoming the barriers or enhancing the stimuli. This was done by developing our own program ideas, by examining those originating in the Office of Toxic Substances, and by canvassing the extensive number of policy proposals that have been suggested, both for TSCA and for other similar regulatory regimes (e.g., pesticides or drugs). This survey covered the positions of a wide range of interest groups from chemical trade associations, to environmentalists, to advocacy task forces for small business.

The sizable body of literature on government policy and technological innovation on which this work is based is presented in the bibliography accompanying this chapter in Appendix D. It includes scholarly reports, Congressional hearings, agency publications, position papers, and popular or trade publications, concerning the following issues:

- government policy and technological innovation, in general
- studies of foreign government policies toward innovation
- reviews of existing U.S. policy
- the relationship between regulation and innovation
- regulatory reform
- small business and innovation

The policy options considered are presented in Table 4.1, arranged according to the principal barrier or incentive toward which a policy is directed or the type of policy mechanism employed. Each of the options is a discrete concept. It is recognized, however, that groups of them could be combined into coherent program packages, as is done in chapter 8. (Note that the options are assigned a letter code - A, B, C, etc. - that is used consistently throughout the report.)

The detailed discussion of each of the thirty-two policy options that follows adheres to the following format:

- A brief statement of each option with its purpose and its rationale
- An explication of the details of the option
- A brief discussion of analogous existing policies, including their success or failure, and
- The advantages and disadvantages of each option.

TABLE 4.1 Policy Options for Consideration

Reducing the Cost of New Chemical Development

A. Direct cost subsidy for general new chemical development via grant mechanism.

B. Direct cost subsidy for general new chemical development via loan mechanism (or loan guarantee).

C. Direct cost subsidy for testing/compliance costs of new chemical development via grant mechanism.

D. Direct cost subsidy for testing/compliance costs of new chemical development via loan mechanism (or loan guarantee).

E. Indirect cost subsidy for chemical innovation generally via tax mechanism.

F. Indirect cost subsidy for testing and compliance costs via tax mechanism.

Increasing the Financial Rewards for New Chemicals

G. Increased patent life for new chemicals.

H. Strengthened trade secret protection by limitations on EPA authority to release information.

I. Decreased taxes on sales of new chemicals.

Increase the Availability of Capital for New Chemicals

J. Increased capital availability for new chemical development via government supported venture capital company.

K. Increased capital availability for new chemical development via tax changes or via SEC rules.

Reduce the Commercial Risk Associated with New Chemicals

L. Reduce risk through goverment financed insurance for regulatory losses.

M. Reduce risk through government procurement of new chemicals.

N. Reduce risk from products liability actions by establishing limits on liability.

Reduce the Cost of Testing

O. Establish government testing for TSCA requirements.

TABLE 4.1 Policy Options for Consideration
(continued)

Reallocations of Cost within the Private Sector

P. Sharing of test data with reimbursement.

Q. Facilitate private sector joint R&D or joint testing.

Information-based Strategies

R. EPA dissemination of chemical information--test results and/or labeling.

S. Chemical technology extension service, including dissemination of information on test and compliance methods.

Changing Market Structure

T. Antitrust action to favor new, small firms in the chemical industry.

U. Tax adjustment to favor small firms or new entrants in the chemical industry.

Improving the Technology Necessary for Compliance

V. Government support to develop new, better test methods.

W. Government support for education and training programs.

Regulatory Changes

X. Actions against existing substitutes for new chemicals.

Y. Fixing time periods for regulatory actions.

Z. Post-market surveillance of PMN's.

AA. Regulatory exemptions for low volume, new chemicals.

BB. Regulatory exemptions for small firms.

CC. Regulatory exemptions for "low risk" chemicals.

DD. "Fast track" PMN's for safe and/or major innovations.

EE. Generic PMN for classes of new chemicals.

FF. Improve EPA staff capability to assess impact of regulatory actions on innovation.

GG. "No-intervention" policy; (i.e., no change from existing TSCA regulation).

For systematic evaluations of the virtues and drawbacks of the options see chapters 6 and 8 in which the policies are evaluated and compared, and in which combinations are examined.

4.2 The Options

A. Direct Cost Subsidy for New Chemical Development, in General, via a Grant Mechanism

A direct cost subsidy for new chemical development is based on the assumption that the social benefits of technological innovation often exceed the private benefits. Because firms often cannot capture all of these social rewards, they tend to "underinvest" in innovative activity from a societal viewpoint. Thus, there is an appropriate role for the government in encouraging innovation through subsidy efforts that will reduce the costs to individual firms.

The subsidy program may be directed at different parts of the innovation process: basic research, applied research, development, or initial prototype manufacture. Most commonly, such programs are aimed at either basic or applied research, on the theory that the government should not be directly subsidizing commercial applications of new technologies, but that its more appropriate role is in the earlier stages of the innovation process, which have less immediate commercial importance.

Such a program may either discriminate among types of applicants or be non-discriminatory. If it is discriminatory, distinctions can be made on a variety of bases. Grants can be given based on a firm's characteristics -- for example, only to small or to new firms. They can also be given on the "value" of the project proposed, which can be determined, for example, by assessing commercial feasibility, social benefits, or the overall persuasiveness of the project proposal; or the grant program may be restricted to the submitters of PMN's only.

If grants were to be administered on a non-discriminatory basis, they would be open to all firms that submitted applications. In this case, they would necessarily be very small. Alternatively, a non-discriminatory program could be keyed to a percentage of the applicant firm's R&D.

This subsidy program's development would clearly require new authority from Congress. It would also represent a major re-orientation in national policy with respect to technical development in industrial firms. The program might or might not be lodged in EPA; however, its mission is sufficiently different from the nature of current EPA regulations that another institutional home would seem more appropriate.

Because of its diffuse nature, this program would require a minimum of about $50 million a year to make any significant impact.

Many developed countries have major programs of this type. Japan, Germany, the United Kingdom, the Netherlands, and France all have grant programs. Although these countries have been committed for some time to this type of subsidy, there is little evidence available to show the overall success of their programs.

Nevertheless, the evidence does show the programs' encouragement of individual projects that may be both commercially successful and of significant social value. However, it can only be presumed that their overall impact is positive. A prerequisite is a cooperative relationship between the government and participating industrial groups .

On the negative side, a subsidy program of this type would be a major departure from existing national policy. It does not particularly favor the goals of TSCA because it is so broad-based. Further,it would be hard to administer, particularly if it were set up on a discriminatory basis. It is politically unpalatable to many, and would be expensive. Lastly, it might be subject to politicization and favoritism.

B. Direct Cost Subsidy for New Chemical Development, in General, via Loans or Loan Guarantees

Loan or loan guarantees for new chemical development in general are aimed at innovation and only relate to TSCA purposes indirectly. They seek to spur innovation by making funds available for research and development (R&D), thus reducing the financial risk assumed by a firm or investors. As opposed to a grant program, however, the government loan is repaid if the chemical is a commercial success. In the case of guarantees, the government assumes a contingent liability that only materializes when private firms fail to meet their loan obligations. For the program proposed here, EPA would be authorized to administer, with the Small Business Administration (SBA), a loan or loan guarantee program for chemical companies seeking to develop new products. Applications would be evaluated by both EPA and SBA.

Loans (or guarantees) could be made up to, for example, $50,000 for basic R&D and $100,000 for product development and commercialization. (These amounts, although reasonable from a political standpoint, may be small relative to real financial need.) A loan could be repaid on a schedule determined as a function of sales. If the venture were a commercial failure it would not have to be repaid. Government loan guarantees would extend to commercial banks, allowing reimbursement in the event a company receiving money under the program defaulted.

The program could be started on a trial basis with a relatively small authority of around several millions of dollars. To have any real impact, however, it would have to be larger. Possible criteria for evaluating applications might include the following:

- o Whether the applicant had been refused a commercial loan first,
- o The company's overall financial situation,
- o Whether the product was for a specific purchaser,

- o Whether the product was merely an attempt to make a "me-too" (i.e. incremental advance from an existing product) or whether it was a true innovation that might be less hazardous than an existing commercial product.

From an environmental perspective, it would be preferable that companies qualifying for loans or guarantees be small firms attempting to develop new products that are low-risk substitutes for existing ones. However, this is obviously a difficult criteria to fulfill when the research has not been done.

This program does not have many existing analogues. Although similar in certain respects to the direct grant program (option A,) a loan program would be more complex from an administrative and financial viewpoint. One possible analogue, the Solar Energy Bank, has not yet had any real experience on which it can be judged.

There are complicated and difficult issues associated with this type of program; its administrative complexity (which EPA is not at this time capable of handling), the need for close cooperation and coordination between EPA and SBA, the size of the program necessary to have an effect on the industry, the uncertain payoffs in actual innovation, and the need for monitoring the loans. In the case of guarantees, while EPA may face very low operating costs, there could be substantial costs later if many companies defaulted.

On the plus side, it would cost less than a direct grants program and, since SBA already has experience with loans, could be integrated with an ongoing activity.

C. Direct Cost Subsidy for Testing and Compliance Costs of New Chemical Development, Specifically, via a Grant Mechanism

This option is intended to directly offset the costs of testing and compliance with TSCA, such as the costs of submitting a premanufacturing notification (PMN). It proceeds on the assumption that some indeterminate fraction of these costs is potentially "undue," thus appropriate for the government to underwrite. These costs may be especially severe during a period of transition as TSCA regulations are instituted. Small firms may be particularly burdened. An important additional goal of this program is to encourage increased and improved testing.

As envisioned, the program would offer grants to all firms submitting an adequate PMN. Adequacy would be an EPA determination in each case; however, most applications that are formally complete should be considered adequate. Grants would vary in size, tied to the size of the costs involved in submitting a PMN. Thus, firms that undertook more testing would receive larger grants. For example, a minimal PMN consisting only of a literature review and a physical property analysis might receive a few thousand dollars; whereas a detailed submission, including chronic toxicity tests on two animal species, might qualify for as much as $100,000.

Grants would be taxable. They would be given automatically, and their processing procedure could be separated from EPA's regulatory activities. A ceiling on total individual firm grants - e.g. $100,000 - should also be established. With this limitation, the program need not be large. An appropriation of about $2 million should be adequate.

To focus this program more closely on innovative companies, the grants might be restricted to new firms, those of a certain size, or those submitting more than one PMN per year.

There are apparently no analogues to this program elsewhere in the government. One of its principal virtues is that it concentrates on the unnecessarily restrictive impacts of TSCA requirements. Moreover, it would be of particular benefit to small firms and new entrants. It should not be excessively costly so long as the number of PMN's and the grant sizes remain small, nor would it be especially difficult to administer. Because grants would be given to virtually all applicants, a major incentive should be created for firms to undertake more testing. This increase in PMN information should greatly benefit EPA, especially since under current law there is no generally applicable testing requirement.

The major problem is probably political; i.e., to make politically acceptable the concept of direct grants to firms to help them fulfill existing legal requirements. This is particularly so for TSCA, since Congress specifically rejected government-funded testing during debate on the bill. Endorsement of this concept for TSCA might also be difficult without extending similar benefits to companies affected by regulations in other areas.

D. Direct Subsidy for Testing and Compliance Costs of New Chemical Development via Loans or Loan Guarantees

The goals of this option, as those of the preceding option, are to reduce a company's immediate cost of complying with TSCA regulations and to promote appropriate compliance efforts. Specifically, the aim is to reduce the cost of testing and compliance by providing loans that would be repaid after the PMN had been accepted and sales started.

The proposed program is basically an extension of the Section 7(b)(5) loan program under the Small Business Act, and it could be administered by the SBA, with technical assistance from EPA. Companies planning to submit PMN's would apply to SBA, which under Section 7(b)(5) of the Small Business Act has authority to grant loans for regulatory compliance purposes. The applications would be evaluated on the following bases (consistent with the existing goals of 7(b)(5)):

- the company must have been refused a commercial loan;

- the protocol it intends to follow must satisfy EPA guidelines for health and safety evaluations and PMN information requirements; and

- the company must have made good faith efforts in the past to comply with TSCA regulations, including previous PMN's it has submitted.

The loans would be for up to 90% of the cost of compliance or $500,000, whichever was less, and would have a maximum maturation of 30 years. The Section 7(b)(5) loans are not forgivable: even if the product fails commercially, the loan must be repaid. However, the program proposed here could also be based on forgivable loans; for example, in cases where testing results were unfavorable enough to dissuade the firm from further development. Loan guarantees could be substituted for loans or could supplement them. They would be for the same amount and would be evaluated on the same basis as the loan program.

Under the Section7(b)(5) program, the appropriate Federal agency (EPA, Occupational Safety and Health Administration (OSHA), Consumer Product Safety Commission (CPSC), etc.) must certify prior to a loan approval that the firm's actions will bring it into compliance, and after the work is done the agencies must certify that the firm is then actually in compliance. This program now offers loans for OSHA, CPSC and Mine Safety and Health regulations. In approximately 10 years of operation, the SBA has granted 571 loans for a total of only $110.8 million. The major reason for the program's small size appears to be that it is actually easier to get a disaster assistance loan or loans guarantee under Section 7(a) than one of the Section 7(b)(5) loans, primarily, it seems, because of the double certification requirement noted above.

In order to avoid this problem in the case of TSCA loans, the second certification could be waived. Because certification is most in issue where compliance technology needs to be reviewed, this requirement could be modified under TSCA. Thus, EPA might review PMN's in advance of the loan to determine at least their procedural sufficiency, rather than attempt to "certify" compliance.

Although this option is closely focused on the goals of TSCA, there are still difficult administrative problems associated with it. For example, while the SBA grants a great deal of autonomy to its regional offices, EPA's Office of Toxic Substances is becoming increasingly centralized, thus making the coordination between the two agencies difficult on a day-to-day operational level. There is also the question of whether the firms will find the requirements for getting a loan so difficult and time-consuming (especially the certification process) that they may find it easier to borrow at higher commercial interest rates.

This option could alter the perceived and actual barriers of the cost of regulatory compliance, and might encourage companies to do adequate health and safety evaluations of new chemicals, thus furthering TSCA's goals.

E. Indirect Cost Subsidy for Chemical Innovation, in General, via a Tax Mechanism

This option is aimed at reducing the costs of technological innovation generally. It is based on the same assumption as the other programs within this category, i.e., that reducing the costs of new chemical development will encourage innovation. It also presumes that the social benefits of innovation may exceed the private benefits, and that therefore there is a role for government in encouraging innovation. It works differently from the other programs however, in that it relies on an indirect incentive, the tax mechanism.

This option would change section 174 of the Internal Revenue Code, which governs research and experimental expenditures. Either one of the following approaches could be taken. The current deduction for R&D expenditures could be increased to, for example, a 200 percent deduction rather than the present 100 percent in the year of the expenditure or capitalization and amortization over the lifetime of the investment. A second approach would be to provide a tax credit for R&D. This would reduce a firm's tax in proportion to the amount spent for R&D. For example, if there were a 10 percent R&D tax credit, this would mean that for every $ 100 spent, the firm's tax would be reduced by $10. Either of these two approaches could be specifically addressed to the chemical industry.

This option has been used by several countries. Canada and Japan use variations of the basic idea, and for many years Germany had an accelerated or increased deduction for R&D, but recently abandoned it. The efficacy of these programs has never been clearly established.

On the positive side, the tax mechanism is presumed to be effective in encouraging R&D. To the extent that R&D promotes technological innovation, so will the tax mechanism. Furthermore, it is equitable and easy to administer once the program is in place.

On the negative side, tax programs tend to be costly. However, because their costs are not directly reflected in new budgetary expenditures, they are difficult to track. The chief criticism of this proposal is that it is not sufficiently aimed at the unnecessarily restrictive effects of TSCA. Also, its effect on new entrants and unprofitable firms is minimal because such firms do not have taxable income against which to use the credits or deductions.

F. Indirect Cost Subsidy for Testing and Compliance Costs via a Tax Mechanism

The purpose of this option is to reduce the costs of testing and compliance by indirect subsidy through the tax mechanism. This option would be used to offset the costs that TSCA imposes as a result of testing and record-keeping requirements, or other compliance efforts. It could apply to both new and existing chemicals. There are three principal approaches to accomplish this purpose. First, it would be possible to increase the current deduction for costs of this type. Under existing law, TSCA-related costs are an ordinary and necessary business expense and are, therefore, entitled to full deductibility in the year in which they are incurred. Under the approach proposed here, an increased deduction would be given; for example, a double deduction for those same costs in the year in which they are incurred.

A second approach would be to have a testing and compliance cost tax credit that would apply to the same kinds of expenses as the deduction. This would be a percentage credit that would reduce a firm's taxes dollar-for-dollar in proportion to its expenses. The third approach is to allow a tax-deductible testing "reserve." This would allow firms to put money into a tax-deductible fund in one year and draw upon it in a future year when substantial testing or compliance costs would be incurred.

Any of these options would require specific legislative approval and amendments to the Internal Revenue Code. This means that the House Ways and Means Committee and the Senate Finance Committee would be involved in creating this policy option.

One of the virtues of this program is that it could be relatively simple to administer since it does not involve a large bureaucracy. On the other hand, the experience with Sections 169 and 104 of the current Tax Code suggest that there may be some problems with determining exactly what kinds of costs qualify for special tax issues. A second virtue is that it will indeed defray a large amount of the costs of TSCA. A third is that because of the tax financing mechanism, the more the firms incur testing costs, the more tax benefits they derive. This is consistent with the goals of TSCA because it tends to encourage testing.

On the negative side, this option would necessitate a major change in the existing tax laws. It violates the principle of tax neutrality and, therefore, would face predictable political difficulty. It would be especially difficult under the tax laws to justify special treatment for the chemical industry when many other industries are also experiencing increased regulatory costs.

G. Increased Patent Life for New Chemicals

This option is aimed at increasing the rewards for new chemicals by lengthening the patent life that may be granted to them. It is based on the assumption that one of the motivating forces for innovation is the size of the financial reward that can be captured by the innovating firm. The program responds to the allegation that the delay necessary in order to comply with TSCA's regulatory requirements effectively decreases the patent life of new chemicals.

This policy option would require new legislation to amend existing patent laws. One approach would be to increase the period of patent protection, for example, by increasing the patent life from 17 to 20 years. This period could apply to all patented products, or only to new chemicals. Another approach would be to provide for an "add on" period to patents for new chemicals. This period would equal the amount of time that the regulatory agency takes to complete its decision making. A third approach would be to start the period of patent protection running when the PMN notification period is completed.

Another approach would not involve changes in patent legislation, but rather, changes in enforcement practices. For example, EPA might attempt to reduce patent infringements. This could be done by using TSCA Section 8 reporting and recordkeeping requirements to identify potential infringement cases.

Other countries have programs analogous to these in some respects. For example, several countries provide for longer periods of patent protection than the U.S. It should be noted that the beneficial effects of patent protection, or of changes in patent protection, on technological innovation have never been clearly demonstrated even though they are widely assumed, both here and abroad.

One of the chief advantages of this option is that it would be very simple to administer once the necessary legislation is in place.

However, it has a number of drawbacks. For example, it appears to have little capability to offset TSCA's impacts and its effect would be felt too far into the future (i.e., 17 years) to create much of an incentive to innovate in the present. If the increased patent protection were restricted to the chemical industry only, it would be difficult to justify politically. If it were not so restricted, the legislative change required would be so major as to render the option politically infeasible at this time. Lastly, the effectiveness of EPA use of TSCA reporting to enforce patent rights is questionable, and an attempt to do so might even hinder the reporting it seeks to encourage for its main regulatory purposes.

H. Strengthened Trade Secret Protection by Limitations on EPA Authority to Release Information

The rationale for this option is similar to that for increased patent life. Trade secrets are a form of protection for intellectual property, which are presumed to encourage innovation by increasing the financial rewards. To the extent that regulation decreases trade secret protection, it creates a disincentive to innovate. TSCA, in particular, may result in such a disincentive because of its comparatively strong provisions that allow EPA to release confidential information to the public. This program would counteract those provisions.

Currently, EPA has regulations governing the use and protection of trade secret information that is submitted to it under TSCA. In addition, there has been litigation between EPA and the Polaroid Corporation on this issue. As a result, the current policies of the agency are fairly firmly established. The only really feasible way of strengthening the protection of trade secrets would be to amend the section of the Act that governs such protection. The kind of amendment envisioned would make TSCA more like other environmental statutes in that EPA would be prohibited from releasing trade secret data to the public.

There are several analogues to this proposal. In most of the other environmental statutes the agencies may not release to the public the trade secret data to which they have access. This option would be modeled on such statutes.

This option would encourage innovation if, in fact, trade secret protection has this effect. On the other hand, it would also substantially weaken TSCA by eliminating a major section of the Act relating to the release of trade secret data to the public when necessary.

I. Decreased Taxes on the Sales of New Chemicals

This option rests on the assumption that increasing the potential financial rewards for new chemicals will, in turn, encourage innovation. It recognizes that regulation may increase costs, and attempts to offset that effect to some extent by decreasing the taxes on profits from new chemicals.

Many measures could be enacted to accomplish this purpose. The simplest would be to decrease the tax rate on profits accruing to new chemicals. But, singling out the chemical industry for such favorable treatment is probably politically infeasible. A more realistic approach would be to provide for deferral of taxes on new chemicals for a period of one, two, or three years when they first are marketed. As a variation, the tax deferral might only be made available if the manufacturer who realizes the income reinvests it in the production of new chemicals for new business. Another approach would be to change the tax treatment of royalties and other licensing fees that are charged for the use of chemical products. These fees are now considered to be ordinary income. This approach would allow license fees to be taxed as capital gains.

There are a number of analogues to these proposals. The Tax Code contains many instances of tax deferral. For example, income taxes are deferred on foreign income until it is repatriated, and capital gains taxes on the sale of personal residences are deferred so long as the gains realized are reinvested in other residential property. Many other types of income are also awarded capital gains status.

These kinds of programs could be expected to be fairly effective in that they substantially increase the awards accruing to new chemicals and thus provide an incentive to innovate. Low or no capital gains tax and investment incentive programs are widely employed abroad.

On the other hand, this option would probably be very costly. In addition, it is so broad-based that it is unlikely to counteract whatever negative impacts TSCA may have on innovation. Lastly, there are equity and political problems associated with special treatment under the tax code for the chemical industry that might make the program unacceptable to Congress.

J. Increased Capital Availability for new Chemical Development via a Government Supported Venture Capital Company

This option in intended to reduce the cost, and increase the availability, of risk capital to firms that undertake new chemical development. It should be tailored to those firms that are most restricted in their access to capital; i.e., small and new firms.

The idea is to establish a new quasi-public corporation that would provide venture capital (either loans or equity interests) to firms in the chemical industry. Its total investment portfolio should probably be in the range of $10 to $100 million. The corporation, which would be funded initially by the government, would be run on a private, non-profit basis, and should be self-sustaining over the long term. It would make investments in new and hopefully innovative chemical companies. It would be able to provide this capital cheaply because of the inital funding base from the government, and also because it would not be under the same kind of profit constraints as an ordinary private corporation. Over the long term, the venture capital company would derive its revenue principally from the capital gains (i.e., appreciated equity interests) that would arise from successfull new chemical firms. Those gains could be used to reimburse the government for the initial capital base. Excess profits could be used to make more loans or stock purchases in innovative ventures.

The corporation would establish criteria on which to judge its investment options. The primary criterion should be the one that all commmercial venture capitalists apply; that is, the commercial profitability of the investment. Because of the special social purposes of this corporation, additional criteria for its investments should include the safety of the chemical products that are being proposed for new development and the size of the firms that apply for the equity investments.

Most other developed countries have programs of this type. For example, in the United Kingdom, the National Research and Development Corporation makes equity investments in firms and makes loans to new ventures that are too risky for a private sector venture capitalist to fund. Similar programs exist in West Germany and France. There is some controversy about whether they have been successful; however, in at least some instances their investments have been financially rewarding.

One of the principal benefits of this option is that it solves, at least in part, the real problem of access to capital that many small and new firms experience. A second advantage is that it is likely to be relatively inexpensive over the long term. The third advantage is that it is directed at new entrants, which would be expected to be more innovative.

One of its drawbacks is that it represents a major policy departure from existing government functions in the U.S. It would establish the government as a venture capitalist in competition with existing venture capital firms, which may not be necessary or desirable. In addition, because this option is directed at new chemical development in general, it cannot be expected to mitigate many of the potential undue impacts that may be associated with TSCA. Lastly, it is possible that the corporation might make so many poor investments that it would lose money.

K. Increased Capital Availability for New Chemical Development via Changes in Tax or Securities and Exchange Commission Rules

This option attempts to decrease the cost and increase the availability of risk capital in general in order to encourage new entrants and innovative firms. It may offset to some extent, the restrictive effects that regulation has, or is said to have, on the availability of capital.

Fiscal, monetary, or money market regulatory policy could be used. Fiscal policies are implemented through the tax system. Capital may be attracted to the money markets via loosened rules for capital gains treatment, a decreased capital gains tax rate, liberalizing the qualifications for Small Business Investment Corporation status, or allowing more lucrative employee stock options.

Monetary policies that affect the supply and cost of capital are generally implemented by the Federal Reserve through changes in the discount rate.

Money market regulatory policies are the province of the Securities and Exchange Commission (SEC). The SEC policy that is generally considered to bear most closely on the problem of innovation and venture capital is contained in Rules 144 and 146. These prescribe a holding period before new privately held stock issues can be resold to the public and, in addition, dictate the rate of resale. As a result, they affect the expected rate of return of a venture capitalist from investments in new firms. The principal policy change that has been suggested in this regard is to change the holding period and rate of resale provisions to allow for a faster turnover and, therefore, a higher return.

All of these policy options have been tried occasionally in this country. Many of them represent only small changes to existing policies or reversions to previous policies. A considerable amount of controversy surrounds all of them, as reflected in several series of Congressional hearings on this problem.

Taken as a whole, these options can be expected to increase the incentive to innovate, even though they are only modest incremental changes from existing policies. Perhaps the most powerful arguments against them, however, are that they do not deal specifically with the problems presented by TSCA. In particular, they cannot be directed at one industry such as the chemical industry. Coordination among the various legislative mandates and implementing would also be difficult.

L. Reduce Risk Through Government-Financed Compensation for Losses due to Regulation

This proposal seeks to lower the risk perceived by a firm or investor at the early stages of product research and development. It would do this by guaranteeing compensation for losses incurred as a result of government regulation, which should encourage investment in risky ventures.

The program envisioned would be a government-supported insurance fund. Initial funding could originate either from general tax revenues or from a specific tax on chemicals (see the discussion of financing options in chapter 7). If EPA regulated a product under Sections 5, 6, or 7 of TSCA, the fund would then reimburse the firm for direct losses due to the regulation (the costs of testing, the market value of the current inventory, and perhaps some percentage of anticipated future losses).

There are very few similar programs at EPA or any other regulatory agency, but the Office of Regulatory Analysis has a major review of this policy alternative underway. The Overseas Private Investment Corporation (OPIC), which ensures against political risks abroad, can serve as a model.

This proposal would certainly encourage companies to research and market products that might be regulated in the future because of potential risk to consumers or the environment. It has two major but possible contradictory effects; while it encourages the development of new products, it could also encourage companies to market less safe products because they would be protected against losses due to regulation. This clearly contradicts the spirit of TSCA.

M. Reduce Risk Through Government Procurement of New Chemicals

This option would guarantee companies with new products a certain minimum market by directing government procurement policies toward new chemicals. The government would create a "market-pull" toward new chemicals that were safer than existing chemicals.

Procurement in the government is carried out primarily by the General Services Administration (GSA), although individual agencies (particularly the Department of Energy and the Department of Defense) do have large internal procurement programs. Under this proposal, the GSA might work with EPA to develop a list of the chemical products purchased by various agencies. It could be authorized to consider substituting new products that appeared to be safer, even if they were more expensive that existing ones. The authorization for this effort could either be made through the annual authorizations of various agencies and departments or as an experimental policy, through amendment of the Federal Procurement Regulations.

The Experimental Technology Incentives Program (ETIP) administered by the National Bureau of Standards, is similar in concept to this proposal. ETIP was started in 1973 as an "effort by the Federal government to learn how to better stimulate the application and use of technology in commercial products and services." Rather than concentrating on one type of product or industry, it sought to perform a number of diverse experiments in technology-forcing procurement. At best it can be said that ETIP's procurement effort has drawn mixed evaluations.

Another type of program, which has no precedents, would not try to substitute safe compounds for existing products but would, in fact, introduce a large new budget item specifically for the procurement of new chemicals. This type of program is obviously less focused, but might be easier to administer. It is certain to have a more widespread effect.

There are several obstacles to the procurement strategy. First, the most effective procurement program is one that is as well-defined as possible, but this would also be the most difficult to administer. For example, the first proposal above might be very helpful to a small company trying to market a new product that would be substitutable for an organic solvent implicated as a possible mutagen. Identifying that company and insuring that it conformed with all of the other procurement requirements might prove so burdensome that the GSA would go back to the large manufacturer of the implicated solvent. There is also the problem of ensuring that the other goals of the GSA--low cost, reliable delivery, and other statutory obligations--are being met at the same time. Finally, in the case of the second option discussed for general new chemical procurement, it is not clear that the government could influence a large enough segment of the overall chemical industry market to make such a broad approach worthwhile. In any event, it would be very costly.

N. Reduced Risk from Products Liability Actions by Establishing Limits On Liability

The possibility of a products liability suit is one of many market risks that the entrepreneur faces. This threat may, to some extent, deter innovation. Recently, it has been argued that the uncertainty in the product liability laws makes it extremely difficult, especially for small or new firms, to contract for adequate product liability insurance, which also is likely to deter innovation. This proposal may encourage innovation by providing an upper bound to the risks involved in product liability actions, and by reducing uncertainty may make it easier to obtain insurance.

Products liability doctrines arise from state court decisions; there is no Federal law of products liability. Therefore, in all likelihood, the policy option considered here would have to be carried out on a state by state basis. A prototype of a uniform Federal products liability law has recently been circulated by the Department of Commerce. However, the possibility of its passage seems quite remote.

There are at least three major alternatives within this policy option. One is to place a dollar value limit on plaintiff recovery in those products liability actions that are based on defects in chemical products. This limit on liability could be coupled with the government assumption of damages exceeding that amount. Another alternative is to enact statutes of repose or statues of limitation that fix the time period over which products liability actions are allowed. A third is that the government could actually assume liability itself, as in the case of the swine flu vaccine.

There are some analogues to this option in other areas. One is the Price-Anderson Act, a Federal law that establishes limits on liability for nuclear accidents. Another is a series of state laws that limit plaintiff recovery to specified dollar amounts in airline accident fatalities.

A favorable aspect of this option is that it increases the certainty with which the commercial risk can be calculated and, therefore, eliminates some of the deterrent that products liability actions may pose to innovation.

One major drawback is that it works a substantial injustice on harmed plaintiffs, because it denies them recovery. However, this can be mitigated somewhat if the government assumes some or all of the liability. Another drawback is that it decreases the incentive to manufacture safe products. Many believe that the threat of products liability actions is, in fact, one of the chief incentives for improving the safety of existing chemical products--precisely because of the uncertainty and high risk associated with products liability recoveries. These risks are likely to be highest for the least safe products. This policy option can also be criticized because it would be very difficult to implement since it would necessitate changing the laws in all 50 states.

O. Establish Government Testing of Health Effects

Another proposal that would reduce the cost of testing and obtaining data as well as increase the industry's confidence that EPA will accept test data, is to have the government establish national test facilities. Such facilities would also increase the EPA's control over test protocols and results.

Because many large firms now have their own testing facilities, a national laboratory would tend to serve small and medium-sized companies lacking in-house testing capability. These firms would send samples of their compounds with a request for the types of tests to be performed. The lab would charge a fee (probably subsidized, in order to compete with private testing labs) for each procedure. The results and sample would be sent only to the manufacturer; EPA would not see the results except as they appeared on the PMN.

This program, which would substantially alter EPA's role in the administration of TSCA, would probably necessitate new Congressnioal authority. The testing could take place either in a government lab

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(within or outside EPA) or in a quasi-public corporation. In both cases, the fee structure could be arranged so as to allow the facility to be financially self-supporting.

While there are government programs that evaluate products for health and safety, there are no facilities that could adequately perform the quantity of tests that would be required for the implementation of this program. Thus, it is not now posible to compare the experiences of these existing programs in order to see how such a facility might be run.

There are a number of objections to this proposal. Companies fearful of jeopardizing trade secrets might be reluctant to entrust their new products to such a facility. Determining the most appropriate size for a facility would be difficult, given the present uncertainty over the extent to which such testing capacity may be required. It is possible that because of both the recent surge of testing facility construction and the uncertainty over the volume of testing to be done, the lab would be underutilized.

The program does, however, offer several advantages: it allows for more scrutiny of protocols, procedures, and test conditions; it is a direct method of controlling the cost of testing; and it increases manufacturers' confidence that test protocols, procedures, and results will be accepted by EPA.

P. Sharing Test Data with Reimbursement

TSCA Sections 5(h)(2)(A),(B), and (C) allow the EPA Administrator to set a fair and equitable reimbursement price when one company uses another company's health and safety data for new chemicals. (We are not concerned here with the reimbursement provisions of Section 4, applicable to existing chemicals.) This helps to insure that the company that did the testing will not suffer a competitive disadvantage because it performs the tests. As now written, these sections apply only to a narrow set of substances: chemicals on the Section 5(b)4 list. The manufacturer of such a chemical may petition EPA for an exemption from the testing requirements if the chemical substance is equivalent to one for which data have already been submitted. The Administration will grant the exemption if additional testing would be "duplicative."

The policy option proposed here would expand the existing reimbursement authority under Section 5, to allow manufacturers of new chemicals to share test data whenever they exist. Procedures for obtaining reimbursement would remain as currently constituted in the Act.

This proposal would be similar to the current pesticide program. EPA might catalogue the PMN's by compound and indicate whether health and safety studies had been performed. This list would be widely distributed so as to be readily available to any company investigating a new compound. The company could then petition EPA and would receive from it the names of all the manufacturers that had either carried out health and safety studies or sought and received exemptions. The company would then contact all of these firms and offer to reimburse them. If the parties could not reach an amicable understanding about appropriate reimbursement terms, the Federal Mediation Service might be able to arbitrate. (Section 5(h)(2)(B) of TSCA, which calls for the Administrator to arrive at a fair and equitable reimbursement by rule when the parties cannot agree, may already permit this.) Another approach would be to key the reimbursement to a percentage of sales (e.g. 5%), in a manner reminiscent of percentage depletion allowances.

EPA has had previous experience with data compensation programs with pesticides, stemming from the Federal Insecticide, Fungicide, and Rodenticide Act of 1972 (FIFRA). Its experience suggests that the administrative determination of "fair and equitable" reimbursement is extremely difficult, so much so that one of the major goals of the 1978 FIFRA amendments was to transfer that authority from EPA to an arbitrator. A similar system under TSCA might require an amendment of the Act.

This approach may be valuable, but its implementation could easily become mired in administrative delay. Even the arbitration arrangement, although apparently an improvement over the previous system, can be quite lengthy. In particular, EPA authority to compel sharing and prescribe reimbursement rates may be necessary to force cooperation from companies reluctant to share their test data. The equity and cost-saving aspects of the program are perhaps its best features. Its potential to promote innovation is probably limited to chemicals that are closely related to those already on the market and for which test results would be transferable. This implies that its effects will probably be greater for existing chemicals than for new products.

Q. Facilitate Private Sector Joint R&D or Joint Testing

This policy option is responsive to the argument that many regulatory costs are "unproductive" from the viewpoint of individual firms. Joint testing of new chemicals or joint R&D on compliance options can reduce regulatory compliance costs to individual firms and perhaps increase the efficiency of the resulting technologies. These benefits, if they in fact exist, may result in more or better testing and compliance methods and perhaps more innovation. The need to allow joint testing or joint R&D may be especially pressing in the case of new and small firms that lack the technical resources to perform tests and to develop new compliance technologies.

This option is basically a question of antitrust policy. Implementing it would involve both the Department of Justice (DOJ) and the Federal Trade Commission (FTC), and possibly new legislation from Congress. There are two separate issues that need to be addressed. One concerns joint testing activities. Here the antitrust problems do not seem to be particularly severe, although there is always the possibility of collusion and monopoly. The second issue is somewhat more complicated. It involves joint R&D on compliance technology development among different firms. This raises a stronger possibility of collusion or monopoly because it involves activities closer to commercial development. In both cases, different policy options are raised when the joint efforts are undertaken by a trade association and when they are undertaken among individual firms.

There are two approaches to deal with these various problems. One would be to provide for antitrust exemptions for all or some of these kinds of activities. This might involve new legislation from Congress, or it might be simply a matter of DOJ or FTC policy. The second approach would be to inaugurate an advisory opinion mechanism from the DOJ and FTC in circumstances of this sort. This would allow the firms who wish to engage in joint R&D the opportunity to be reasonably certain about the antitrust implications of the venture before they begin, and might be an improvement over existing antitrust policy, which some people allege is uncertain in this regard.

Joint R&D for compliance technology, and joint testing, are common practices abroad. The antitrust laws in most developed countries are quite different from those in our own, and the practices described in this policy option are not seen to pose any serious social danger. The one analogue in this country is the experience of the automobile industry. In 1969, the DOJ brought an action against the automobile industry for collusion and conspiracy with intent to frustrate the pollution control laws. This action resulted in a consent decree between the government and the industry that prohibited automobile firms from engaging in joint R&D. IN 1979, as a result of another court action, this restriction was lifted and cooperation among members of the industry is now allowed.

This policy has the virtue of not requiring any new financial commitments. In addition, it would probably be of most use to the new and/or small firms that are most in need of cooperating in regulatory compliance efforts.

On the other hand, this option may contravene the goals of antitrust policy and contradict established procedures of the antitrust enforcement agencies. It should also be recognized that cooperative activities among regulated firms raise the possibility of collusion, not only to monopolize certain portions of the industry but also to frustrate the intent of different regulations. Lastly, this option appears to be more valuable when the costs of compliance technology are extremely high (for example, for air pollution devices or major chemical process changes) than in the case of the individual regulatory requirements under TSCA, no one of which is likely to be very costly.

R. EPA Dissemination of Information: Test Results and/or Labeling

The main goal of this proposal is to create favorable market environments for safer chemicals. By publishing the results of health, safety, and exposure studies and/or labeling products with health and safety information, consumers can be encouraged to purchase products with safety as one criterion. This should provide a "market-pull" for safe chemicals and encourage product substitution.

For the labeling option, EPA would issue guidelines specifying the kinds of information that must be shown on the product's label. Information like acute toxicity levels, effects observed during animal studies (including statistically significant increases in tumor formation), exposure studies, and suggested limitations on use might be included. A simpler alternative is to allow for an EPA approval on the label. These options might require new statutory authority because they go rather far beyond existing policy -- both in terms of information disclosure requirements and in terms of EPA product endorsements.

The option to disseminate test results would involve EPA itself in such activity. Essentially, it means a much more vigorous use of TSCA Sections 6 and 14 authority. To minimize any problems that might arise with respect to data confidentiality, EPA could release test data and the product names only without disclosing any confidential identities. However, companies often claim confidentiality for this information. The second option, labeling, would not create confidentiality problems. It has the obvious advantage of immediacy to the consumer, but is probably more difficult to implement than the dissemination of test results because of its product endorsement aspect.

One analogue is the Food and Drug Administration's (FDA) labeling program. There has been consistent opposition to FDA labeling rules in the past. One important lesson that the EPA can learn from the FDA's experience is that the form the information takes can play a major role in the amount and kind of opposition engendered. It can be argued in the case of drugs that much of the information printed on the label is incomprehensible to the average consumer. However, the greater the simplification, the more interpretive of the data the labels will become. Striking a balance satisfactory to all parties will probably be the most difficult part of any labeling program adopted by EPA. EPA and OSHA are currently in the process of developing generic labeling programs that will, of necessity, address this issue.

These policy options have the virtue of being inexpensive to the government. They probably do not require new legislation, and are entirely consistent with the purposes of TSCA. They may be effective in promoting new safer chemical products, and they work through the establishment of market incentives on the part of consumers. Their chief drawback, however, is the difficulty the EPA would face in balancing the public "need to know" with the desires of manufacturer's to protect their trade secrets. The inability to achieve a proper balance of these factors could have the effect of impeding the flow of health and safety information from the companies to the agency.

S. Chemical Technology Extension Service, Including Dissemination of Information on Test and Compliance Methods

This option is targeted at the variety of problems that arise in the development of new technology, both generally and for compliance with regulation. Its objective is to reduce costs, either those associated with developing new technology or those resulting from compliance with regulation. Furthermore, this option assumes that the existing body of technical knowledge can be better utilized. It would, therefore, attempt to bring lagging firms up to the state-of-the-art in various technical areas by disseminating the latest knowledge and providing consultation. It is particularly targeted at the differences in the knowledge base among various firms in the private sector, and would emphasize the special needs of new and small firms. Lastly, it assumes a lack of knowledge about applicable regulations and how to comply with them, and would seek to remedy both of these deficiencies by the dissemination of regulatory information.

The basis for this program would be a network of technical centers and technical extension agents. The centers would be responsive to inquiries from firms in the private sector, and would provide an institutional affiliation for the technical agent. The agents would comprise an out-reach program to visit and consult with individual firms. Both would attempt to foster technological innovation in the private sector. Their special mission would be to disseminate regulatory information and information about compliance technology.

The centers and agents would be federally funded. However, because of the decentralized nature of the program's services, it would have to be implemented and run on a state and/or local level. The funding base would have to be quite large in order for the program to make any significant impact. It is estimated that approximately $50 to $100 million a year would be needed for a major impact, although smaller experimental efforts could be undertaken.

There are three analogues to this program in use today in the United States. One is the Agricultural Extension Service, which has been extremely successful in disseminating agricultural technology to farmers in this country throughout the last century. The second is a group of approximately 30 state technical centers, authorized by the State Technical Services Act. Thus far this program has been implemented on only a small scale, and has not dealt at all with regulatory problems. The one similar program that deals with regulatory issues is OSHA's state-level consultation program, which is restricted to a single regulatory area and is funded at a modest level.

The principal virtue of this proprosal is that it is likely to be quite effective in improving the knowledge base of some firms in the private sector and in improving the uses of existing technologies. Its chief negative aspect is that it would be very expensive. In addition, it would be difficult to implement, since it relies both on a federal program and a multiplicity of state or local programs. Lastly, it can be faulted because it is not targeted well at the particular problems that TSCA raises and would do little to offset its impacts on innovation. Indeed, the problems of compliance with TSCA, especially for new chemicals, may not be as susceptible to technological solutions as other regulatory problems.

T. Antitrust Action to Favor New Small Firms in the Chemical Industry

This option is based on the assumption that monopoly power, perhaps more than regulation, is a significant barrier to innovation in the chemical industry. It assumes that innovation will be increased if competition in the industry is increased. It is intended to favor smaller and newer firms that would probably find it easier to survive if the large existing firms in the chemical industry were broken up.

This policy option could be implemented in several ways. First, it could be accomplished by new antitrust legislation. For example, firms of a certain size could be legislatively specified as *per se* violators of the antitrust statutes. This kind of proposal has been considered intermittently by Congress during the last five years or so, with very little legislative success. Another approach would be to have more vigorous enforcement of existing antitrust legislation, which would have to be pursued by the DOJ and FTC. A third approach would be that various legislative and/or administrative mechanisms could be used to make mergers more difficult, for example, strong pre-merger clearance procedures.

As far as can be ascertained, there are no analogues either in this country or abroad to this kind of program. There have been no major recent antitrust actions taken against an industry quite so large and complex as the chemical industry. To the extent that competition actually does foster innovation, and antitrust action against the chemical industry would indeed increase competition, this option would be beneficial. It might also have favorable political or social side effects. On the other hand, it would be extremely difficult to implement properly. It would not be easy to determine, for example, on exactly what basis to break up the existing firms and what kind of new entities would be most advantageous. Furthermore, antitrust actions are usually undertaken on a case-by-case basis and can involve years of litigation. This option could also be criticized on the basis that its connection to the goals of TSCA is very tenuous, therefore, it would have little capability of offsetting the unnecessarily restrictive impacts of TSCA.

U. Tax Adjustments to Favor Small Firms or New Entrants in the Chemical Industry

This policy option is based on the assumptions that small and new firms tend to be more innovative, and that regulation affects them more severely than it does large firms. It should be recognized that neither of these assumptions has been proven. (See chapter 2 and appendix B.)

The program would operate through the tax mechanism, which has the advantage of minimal government intervention and is likely to be efficacious. A variety of specific tax measures could be implemented to reduce the tax rate for new and/or small firms. In order to favor small firms, one approach would be to loosen the requirements necessary to qualify for subchapter S corporation benefits. A second approach would be to provide a period of tax deferral for new entrants into the industry. Both approaches would require new legislation and would have to originate in the committees having jurisdiction over taxation rather than in those having jurisdiction over TSCA.

None of the mechanisms proposed here is new; they are essentially incremental variations or additions to existing tax programs. There has been substantial policy debate about all of them for several years. Congress has not yet seen fit to carry many out, although the loss carry-forward provisions have been liberalized in recent years. This has allowed greater profits to new firms after the first few years of operation in which they usually experience losses.

These programs, considered as a package, would probably be helpful to small and new firms, and even be effective in changing industry structure to some extent. On the other hand, they are almost irrelevant to the aims of TSCA. In addition, because they substantially reduce taxes, they are likely to be very expensive.

V. Government Support to Develop New, Better Test Methods

This option provides government support to improve test methods relevant to TSCA. It casts the government in a traditional role that is widely acceptable. Its justification is that private firms do not fully benefit from all the social rewards that improved testing would yield, therefore government support is warranted. Such support is not likely to decrease the cost of compliance substantially, but it could improve signifcantly the quality of compliance efforts.

Government support can be provided via a variety of mechanisms. In theory, grants could be given to private chemical firms, but this would be quite controversial. More reasonable alternatives include research grants and contracts to universities and non-profit institutes or work in government laboratories.

Currently, there is a considerable amount of work going on along the lines proposed here, funded for example, by EPA and the National Institutes of Health (NIH). An assessment of the quality and quantity of this existing activity would be needed to appropriately judge the potential effectiveness of the policy options suggested here.

W. Government Support for Education and Training Programs

Since all environmental regulatory programs must ultimately be implemented through the efforts of highly trained individuals, a new regulatory regime creates new personnel needs in both the public and private sectors. This is particularly true of TSCA, which relies to such an extent on product testing. The government has traditionally assumed the role of funding education and training (either directly or through the research contract mechanism) in areas related to new national needs. The space program is one outstanding example. The proprosal here is to apply traditional modes of educational support to the needs created by TSCA.

This policy option would be implemented primarily through the university system. Government support could be for internships, fellowships, or contract research in TSCA-related disciplines -- toxicology, biology, genetics, epidemiology, etc. Outside of the universities, programs could include retraining and internships. These might be funded directly or through special tax provisions for the educational expenditures of private firms.

It would be expected that this policy option will generate little controversy. It exhibits a clear special benefit, and is consistent with longstanding notions of the appropriate governmental role. One argument against such training programs is that they do not show results until after the national need is past because of the long lead-times involved in university education. In addition, it has been argued that the availabilty of scholarship or research funding in a particular field attracts more students to it than the actual demand warrants, resulting in eventual oversupply. These disadvantages may be overcome, however, by shorter-term retraining programs.

X. Actions Against Existing Substitutes for New Chemicals

This policy option attempts to increase the market incentive for new, safer chemicals in the chemical industry. It recognizes that there are always substantial market barriers to the introduction of new products, especially for those that are safer but more expensive than existing substitutes. While one of the purposes of TSCA is to increase the safety of chemical products on the market, the regulatory regime that the Act establishes is more rigorous for new chemicals than for existing chemicals. This proprosal would provide one means to equalize new and existing chemicals. It relies on regulating the existing substitutes for new, safer chemical products rather strictly. It is hoped that thereby the development of safer and more innovative new chemicals would be fostered.

The program would begin when a PMN is filed. Action would then be triggered against an existing product (or products) substituting for the product covered by the PMN. This would take place in addition to whatever action is taken on the PMN. There are a variety of actions available to EPA in this regard. One approach would be for EPA to establish a kind of presumption of unreasonable risk associated with the existing substitute whenever a PMN is filed for a safer new chemical.

Procedures to require testing could then be commenced. Another approach might be to release whatever test data EPA has access to on existing chemicals when a PMN is filed for a product that could be a substitute. A third would be to release a briefing to the public whenever a PMN on a new, safe substitute for an existing chemical is filed.

As far as can be ascertained, no analogues exist in any of the existing regulatory programs either in this country or abroad.

This option has the virtue of providing a strong incentive for safety. In this regard, it is highly consistent with the aims of TSCA. Also it requires no new legislation. On the other hand, it poses rather severe difficulties in implementation. For example, it will be very difficult for EPA to make relative risk decisions, to discriminate properly between new and existing products, and to be certain about its determination that the new substitute is actually safer than the existing product. Lastly, political controversy may be engendered, particularly by those firms which have been adversely affected in the market by the publicity that the new substitute products have received from EPA.

Y. Fixing Time Periods for Regulatory Action

This option is addressed to the problem of uncertainty in regulatory actions. One of the criticisms that business interests have leveled against regulatory agencies is that their requirements change over time, thus making it difficult for business to plan. Innovation may be impeded in this climate of uncertainty.

The policy option considered here would set a fixed time period for individual regulatory actions. For example, the agency might agree not to contact an applicant firm or review its product, except in extraordinary circumstances, for a fixed period of time following submission of a PMN, presuming no action were taken by the agency on the PMN within the normal review period.

As far as can be ascertained, this policy option has no analogue in other regulatory areas. It has the advantage of increasing the private sector's perception of certainty in regulatory decision-making. On the other hand, it has a variety of disadvantages. For one, it is not likely to be especially effective in offsetting whatever undue impacts TSCA may have. For another, it tends to deprive the regulatory agency of needed flexibility, especially in circumstances where new environmental, safety, or health hazards come to light. When such problems arise there is an imperative to protect the public. Therefore, it is difficult to see how such a policy option could provide sufficient degree of certainty while still protecting the public from unreasonable risks.

Z. Post-Market Surveillance of PMN

This policy is addressed at two distinct problems in the TSCA regulatory system. For one. the decisions on PMN's are often seen as "all or nothing," in which a positive decision on the PMN is often the final action that the agency takes against the chemical. This has the drawback of hindering the agency's reconsideration of its action when new health and safety data come to light. Often, in the face of this dilemma, it will be forced to resolve its doubts about the PMN determination in favor of safety, and keep new products off the market. The post-market surveillance option allows EPA not to take action on products that it otherwise might while continuing to watch them over a period of years until it is certain about their environmental, health, or safety consequences.

There is a clear analogue to this program in the post-market surveillance efforts that have taken place under the Food, Drug, and Cosmetic Act in the regulation of new drug applications.

This option has the virtue of allowing innovations to be marketed that otherwise would not have been. On the other hand, it poses some health, safety, and environmental risks to the general population and, to the extent of these risks, may be inconsistent with the goals of TSCA.

AA. Regulatory Exemptions for Low-Volume Chemicals

This is the first of a series of three proposals that would exempt different classes of chemical products or manufacturers from certain provisions of TSCA. These exemptions could apply to the submission of PMN's or to any other regulatory requirements under the Act.

The assumption underlying this proposal is that for chemicals that are produced in small volumes the risks are less than the potential benefits. These exemptions would be applied to any company that produced less than a certain volume of the chemical in question, regardless of the size of the company involved. Thus, both large and small producers would benefit. However, since EPA's concern is not only with the possible exposure of workers but also with general human and environmental exposure, it might be necessary to impose a total production ceiling over which producers would have to start submitting PMN's.

Although there have been proposals to exempt small businesses from regulatory requirements under different environmental laws (see option BB), this program has no exact analogue. All R&D chemicals are exempted under TSCA.

This exemption is likely to stimulate the innovation of new chemicals, since producers would be confident of being able to market without regulation or mandatory reporting of known health and safety data. This would apply particularly to specialty chemicals for unique purposes. EPA would also be confident that if the chemical turned out to be a major innovation, it could always be regulated at a later time when the volume ceiling was exceeded.

However, this exemption could be a major impediment to the effort to control environmental exposure to potential chemical hazards. The effects of a highly persistent chemical that was produced in small volumes for several years could be significant and long-lasting. In addition, without the submission of PMN's, even if EPA discovered that a new chemical was a potential hazard, there would be logistical problems in locating and regulating its manufacturer. Lastly, the program's aim could be circumvented by the proliferation of small companies, each producing volumes just below the exemption limit.

BB. Regulatory Exemptions for Small Firms

This exemption from all of the TSCA regulatory requirements would apply to small firms, on the assumptions that they may be more innovative than large ones and are less able to bear the costs of regulation.

The designation of firms as small could be based on the number of employees (as the SBA does), on the volume of sales within the firm's manufacturing cohort, (e.g., its four-digit SIC code or on some other measure of size).

There have been efforts to exempt small businesses from the requirements of Acts such as the Occupational Safety and Health Act, but there is no good precedent on which to gauge the possible effects of this exemption from TSCA. Also, TSCA itself exempts small firms from certain requirements, notably those of Section 8.

Such an exemption would result in lower regulatory costs for small businesses , and would probably promote innovation. However, there are several arguments against it. First, there is no evidence that small companies produce only small volumes of chemicals. This is particularly true when the criterion for size is number of employees. Second, there is some reason to believe that the working conditions in small companies may be less safe than in large firms. This could lead to an actual increase in human exposure that would be proportionally greater than if a firm's exemption was based on the volume of a particular chemical it produced (option AA).

CC. Regulatory Exemption for Low-Risk Chemicals

This last exemption from the TSCA requirements would be applied to chemicals that were judged by EPA to be low risk. As such, it would be related to the generic PMN (option EE) and the fast-track option (option DD). The assumption is that it is possible to predict on the basis of structure-function relationships, chemical family classification, and prior experience, whether a new compound that has not undergone extensive health/safety evaluations will present an unreasonable risk of injury to human health or to the environment.

EPA would prescribe guidelines (as in the preceding two cases) for exemptions classified according to chemical family, molecular weight, or class (e.g., definite structure or indefinite structure). This would have the effect of driving innovation in the direction of safer categories.

As in each of the two preceding exemptions, EPA could expect major controversy over the definition of the exempted category, particularly in this case, however, since EPA would often be basing determinations about "safety" on very limited actual or theoretical evidence. Therefore, while this basis for exemption is more consistent with the overall goals of TSCA in that it seeks to rank chemicals on the basis of perceived risk, it is questionable whether EPA or anyone has the necessary knowledge and skill to perform such a ranking. In addition, these determinations, which would be very controversial initially, could become even more so if they ultimately prove incorrect. Thus, they could be seriously damaging to the agency's credibility.

DD. "Fast-track" PMN's for Safe and/or Major Innovations

The fast-track program is a method of cutting down on the time involved in the PMN process. Compounds that qualify would receive rapid reviews and actions. In order to qualify, a potential producer would declare that a new compound is low-risk, or that it is as safe or safer than one already in use. Since the notification period under TSCA is a maximum of 180 days, delay is not generally considered as important a factor under TSCA as it is for approval of a new drug or pesticide. Nevertheless, some specialty compounds or other products that require short turn-around times may benefit from this policy, There is, however, no way to estimate the number that would be affected.

The fast-track would not be expected to play a significant role in accelerating innovation overall, but could be useful in some cases. As with the exemption for low-risk chemicals, there is likely to be strong disagreement about whether a specific chemical should be fast-tracked.

EE. Generic PMN for Classes of New Chemicals

This program would greatly simplify the PMN procedures for those chemicals and innovations judged by EPA to be low-risk. It would allow classes of new chemicals to be reviewed as a group by EPA. Rather than exempting these compounds, however, this proposal would decrease the reporting requirement on the PMN. For example, lists of all known safety and health data, volume, or manufacture, and so on could be reported for the class rather than for each individual chemical.

This option has been suggested in connection with the FDA approval of drugs. It has the advantage over the regulatory exemptions (see option CC) of providing EPA with a data base in the event it were to become necessary to regulate the chemical at some future time. Furthermore, it does not tie EPA's hands as an exemption might. The same problem exists, however, of determining which categories of innovations are low-risk. Thus EPA could anticipate facing similar (but less intense) controversies than with the regulatory exemptions.

FF. Improved EPA Staff Capability to Assess the Impact of Regulatory Actions on Chemical Innovation

A number of criticisms have been leveled against regulatory agencies by business interests. One is that these agencies are not sufficiently sympathetic to the problems of business. A second is that they do not have adequate knowledge of business practices. A third is that agency personnel do not have sufficient technical expertise. And a fourth is that insufficient analysis is undertaken before regulatory actions are concluded. This option proposes a mechanism to respond to these kinds of criticisms.

The proposal is based on the assumption that better informed action on the part of the regulatory agency will result in a smaller negative impact on innovation. There are many actions that agencies can take in this regard. For example, industry - government personnel exchange programs have been suggested. This might involve amending of the Intergovernmental Personnel Loan Act to apply to exchanges of personnel between the public and private sectors. Another possibility would be to provide more training on the analytical assessment of the consequences of each regulatory action on technological innovation.

There are a variety of analogues to these kinds of programs in other regulatory areas. For example, there are already several different kinds of impact statement requirements that have been imposed on regulatory agencies within the last few years. These tend to delay regulatory action and to impose new administrative costs. On the positive side, it can be presumed that the kinds of programs proposed here can only help EPA's decision-making. However, the degree of improvement may not be very great. Lastly, the delay in regulatory action resulting from additional analysis could impede the achievement of the aims of TSCA and other regulatory legislation.

5. A PROCESS FOR ASSESSING THE POLICY OPTIONS

In chapter 3 a basis is developed for understanding how TSCA might have unnecessarily restrictive impacts on the process of technological innovation. Chapter 4 then presents a wide variety of policy options for offsetting these impacts. In this chapter the process by which these options were assessed by the project team is explained.

There are three reasons that the construction of an elaborate economic model to estimate the costs and benefits of the options was neither feasible nor appropriate: 1) currently available economic models generally cannot adequately address the dynamics of technological innovation, 2)the data needed for such an assessment are lacking, and 3) factors other than relative costs and benefits, such as administrative feasibility and effects on the primary goals of TSCA, are necessary inputs to the decision process. Therefore, the assessment procedure used in this study is based on a less rigorous, although structured, analytic approach known as Magnitude Estimation Group Scaling.

5.1 Criteria for Assessment

Any proposed policy option must be evaluated on the basis of certain general criteria: whether it can it be implemented; whether it will work if implemented; what it costs will be; and whether its implementation will lead to any further problems. Each of these broad criteria can be subdivided; e.g., both private and public costs must be taken into account.

For this project, a detailed set of evaluation criteria was first developed. (They are presented in appendix C.) From these, eight fundamental criteria for policy assessment were selected:

1. Capacity to countervail
2. Private costs
3. Public costs
4. Administrative feasibility
5. Time to implement
6. Supportive of TSCA's aims
7. Other side effects
8. Political feasibility

Subsequently, two other criteria were added. Criterion 9, "initial policy rating," which is an initial estimate of the overall rating of a policy made without reference to the detailed criteria, and criterion 10, "effectiveness," which represents a combination (the product) of a policy's capacity to countervail and its adminstrative feasibilty.

Capacity to Countervail

This criterion captures the ability of a policy option to offset the unnecessarily restrictive impacts of TSCA on innovation. As with all the criteria used in assessing the policies, the capacity to countervail was judged independent of cost or any other factors. However, it does take both the direct and indirect effects of policies into consideration.

Private Costs

While it might appear that policies to stimulate innovation should not create new private costs, this criterion is designed to capture whatever private costs may accrue from taking advantage of or complying with a policy. Many innovation stimulating policies could require additional record keeping by a firm. These costs could offset some of the expected benefits to the firm, or might discourage smaller firms from utilizing the program.

Public Costs

This criterion is designed to assess only the direct public budget outlays for a policy, without regard to a cost's possible mutliplier effects elsewhere in society.

Administrative Feasibility

This criterion assesses the ease with which a policy option can be effectively administered. Restraining factors are limits on the administering agency's number and quality of staff, the level of information needed to effectively carry out a policy program, the expertise necessary to assess this information, and whether the program complements or conflicts with the existing operations of the administering agency.

Time to Implement

If it is decided to adopt a particular policy, there is generally a time delay until it actually can be implemented and another time delay until the benefits are enjoyed. This criterion captures the overall time delay between the decision to adopt a policy and the point at which it is effectively operating to counter any unnecessarily restrictive impact on innovation.

Supportive of TSCA's Aims

Some policies to stimulate innovation (e.g., the exemption for low volume chemicals) act to thwart the main purpose of TSCA, while others may encourage the innovation of safe chemicals. This criterion captures the degree to which a policy option is supportive or non-supportive of the primary TSCA goal - protecting against unreasonable risk of injury.

Other "Side Effects"

Policies to stimulate innovation may have other effects unrelated to innovation per se. Some policies, for example, may give a competitive edge to large firms, while others may give rise to improved toxicological testing methods. While judging the net positive or negative nature of these side effects is somewhat subjective, the extent to which they support other publicly mandated purposes may be thought of as positive, and side effects that act conversely may be thought of as negative.

Political Feasibility

This criterion is difficult to evaluate independently from the others because the level of public expenditure as well as other criteria will also be reflected in political judgments. Nonetheless, policies that require new legislative authority may be less feasible than those that do not. Among those requiring Congressional action, some may be inherently more acceptable. Furthermore, other Executive branch agencies may be more or less supportive of a policy initiative. This criterion reflects the views of the project team members regarding the objective political reality to the extent feasible, rather than their personal preferences for political action. Because it is felt to be more subjective and less analytical than the other criteria, political feasibility was not considered in the overall policy ratings discussed in section 5.2 and in chapters 6 and 8.

5.2 A Screening Process

A procedure to elicit judgments from the project team was employed in assessing the policy options. The purposes of the procedure were to gain insight into the relative merits of each policy, and to stimulate structured examinations and discussions of the policies. These purposes are reflected in the qualitative discussion of options in chapter 4 and in the rankings discussed in chapters 6 and 8.

5.2.1 A Brief History of the Use of Group Judgment Methods

Group judgment procedures are now in common use as aids to decision-making in business, government, and other institutions. While there are many variations in practice, group judgment procedures have many common elements. Usually, combinations of elicitation forms and group discussions are used. It is common to keep choices limited to a small set of questions, options, or alternatives. Often, the procedure is carried out in several phases. For example, there might be an open-ended elicitation phase where participants are queried for options, a closed-ended evaluation phase, and a second round of elicitation and evaluation to facilitate greater closure on a final set of evaluations.

While some equate group judgment procedures with the Delphi process, it is actually only one of many processes in use. Dalkey and Helmer originally used the Delphi process as a means of minimizing conforming influences by eliminating face-to-face discussions and having respondents remain anonymous. Others, such as Delbecq, et al. (1975) have employed a procedure called the Nominal Group Technique as a means of augmenting discussion approaches. Priest (1978) developed a factor analytic* variation of group judgment techniques that is suited to complex problems.

5.2.2 The Procedure Followed in this Project

The group judgment procedure used is a factor analytic Magnitude Estimation Group Judgment technique that employs several criteria for judging the policy options. The advantage of a factor analytic approach is that individuals are often better able to judge the merits of alternatives if their decision process considers every one of the several factors that determine the merits of each choice.

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*In a factor analytic approach to decision-making, the decision rule is decomposed into several sub-rules, each of which is decided separately. Then the separate decisions are recombined to yield the overall decision.

The magnitude estimation approach involves judging the number of times one alternative is better or worse than another. It is particularly useful for setting up a rating scale having a wide range. In this analysis, one policy could be judged as anywhere from 10,000 times worse to 10,000 times better than another, along each criterion. While it was not expected that participants could make very meaningful distinctions at the extremes of the scale, these were made available for expressions of emphasis.

Another characteristic of this method is the use of an anchor policy, which can be any reasonably straightforward policy. It was discussed at length so that the participants understood and agreed upon the criteria as applied to the anchor. All other policies were then judged in comparison with the anchor policy, which was assigned an arbitrary rating of 1.0 for each criterion. Thus, a rating of 1.0 for a policy option on one of the criteria means that it was judged equivalent to the anchor option on that criterion.

The policy options were discussed by the group before they were rated. Each participant was then asked to conceptualize the best possible specific policy under each of the more general policy categories, and to rate that policy option in comparison with the anchor option. Using this approach, each policy was placed in the best possible light by each participant. (The raters wrote notes on their best conceptualized policies, that were incorporated into the discussions of the policy options in chapter 4.)

5.2.3 Group Judgment Elicitation Sheet

The eight criteria listed in section 5.1 were used to assess the policy options in chapter 4. These thirty-two policies were rated by six project participants using the rating sheet shown in figure 5.1. Every rater was asked to assess how each policy stood with respect to the anchor policy on each of the eight criteria. In addition, an overall rating compared with the anchor was requested. The anchor policy was

Figure 5.1 Rating Sheet

Rater____________________________________

Program to be Rated____

____

PROGRAM RATING

	Capacity to countervail	Private costs	Public costs	Administrative feasibility	Time to implement	Support TSCA aims	Other "side" effects	Political feasibility	Overall Program Rating				
Anchor Rating	1	1	1	1	1	1	1	1	1				
Program Rating													

Description of best program of this type:

Advantages of best program of this type:

Disadvantages of best program of this type:

Other Comments:

described in a document circulated with the evaluation sheets, which is shown in figure 5.2. The anchor policy was assigned an arbitrary value of 1.0 on each criterion. The individual raters then assessed how much better or worse a policy was on each criterion relative to the anchor program. For example, if the individual believed that a "Direct cost subsidy for general new chemical development via a grant mechanism" was likely to be twice as feasible administratively than the anchor policy, the rater would enter a 2.0 in the appropriate column. The criteria sheet used in the rating process is reproduced in figure 5.3.

5.2.4 Group Judgment Integration Model

To integrate the judgment of the six raters on the eight criteria, a heuristic, quantitative model was developed. The model cannot be derived from first principles; instead, it represents a plausible formulation of the relationships involved. The calculations were done using a simple computer program.

Because the rating system involved a multiplicative judgment, the model entailed taking a geometric mean of the ratings on the different criteria. Furthermore, since the criteria were judged by the group to be of varying importance, their ratings were weighted differently in the model. The judgments of all participants were weighted equally.

First, the rating of each policy on each criterion was calculated by taking the geometric mean of the ratings for the six raters, as follows:

$$\begin{array}{l}\text{Rating for}\\ \text{policy } n \text{ on}\\ \text{criterion } j\end{array} = \left[\begin{pmatrix}\text{Rating by}\\ \text{person 1 on}\\ \text{criterion } j\end{pmatrix} \times \begin{pmatrix}\text{Rating by}\\ \text{person 2 on}\\ \text{criterion } j\end{pmatrix} \times \ldots \times \begin{pmatrix}\text{Rating by}\\ \text{person 6 on}\\ \text{criterion } j\end{pmatrix}\right]^{1/6}$$

Next, an overall rating for each policy was calculated by taking the geometric mean of the ratings on the first seven criteria, weighted by various factors as follows:

FIGURE 5.2 Anchor Program Description

ANCHOR PROGRAM: #3 - DIRECT COST SUBSIDY FOR TESTING/COMPLIANCE COSTS OF NEW CHEMICAL DEVELOPMENT VIA GRANT MECHANISM

Program Description

One best program of this type might have the following features:

1. Grants would be offered to firms submitting an adequate PMN.
2. The size of the grant would be tied to offsetting a substantial fraction of the costs of testing, literature review, and PMN submission. (Better PMN's would earn bigger grants.)
3. These costs and grant levels would be established by EPA based on a cost analysis, updated periodically.
4. Typically, grants would range from, say $5000 for a minimum PMN with only physical properties and a bare literature review, to say, $100,000 for an extensive PMN including chronic toxicity test results on two animal species.
5. EPA would offer the grants automatically, once the adequacy of the submission for each grant level were determined. The grant award process would proceed separately from all testing/regulatory actions taken by EPA based on the PMN.
6. Each firm would be limited to annual total grants of, say $100,000, which would include one or more awards.
7. The EPA would seek an annual appropriation of two million dollars for grant awards. Supplementary appropriations could be sought to cover overruns.
8. No other limit on grant availability such as "first come-first served" or a lottery would be used.

Discussion

1. This program would tend to offset directly the costs of testing and PMN submission. Some, essentially indeterminate, fraction of these costs are undue, arising from transition effects and possible unfair and inefficient costs for small firms.
2. The aggregate grant limit tends to favor small firms, while the taxable feature tends to favor new entrants and marginal firms (little or no tax) while recovering some portion of the grant from profitable firms that need it less.
3. By giving larger grants for more complete PMN's, the program tends to encourage firms to do more testing and analysis for new chemicals.

Figure 5.3 CRITERIA FOR INITIAL ASSESSMENT OF GENERAL PROGRAMS

(each criterion, ceteris paribus)

1. Capacity to Countervail - the inherent capacity of the programs to offset the undue innovation damping effects of TSCA regulations once it is put in place. This rating should reflect the capacity of the programs to mitigate these effects in total, not only for one specific class of chemicals or one type of innovation barrier.

2. Industry Costs - relative to the base program, are the private industry costs of the program higher (less than 1) or lower (greater than 1).

3. Public (Government) Program Costs - relative to the base program, are the budget costs of the program higher (less than 1) or lower (greater than 1).

4. Public Administrative Feasibility - relative to the base program, how feasible is it to make the program work (e.g., obtain and process the information necessary to implement the program, obtain the necessary size and mix of staff capabilities, etc.).

5. Time to Implement - relative to the base program, to what degree does the time required to make the program operational make the program better (greater than 1) or worse (less than 1).

6. Supportive of TSCA Aims - how well does the program support the main purpose of the TSCAct.

7. Other "Side" Effects - are the net other effects of the program (e.g., market changes; distributional inequities; effects on consumers, workers, and the public) more or less beneficial than those of the base program.

8. Political Feasibility - how likely is it that new legislation can be obtained if needed, or that the program will be acceptable to the legislative branch (authorizing and appropriation committies, etc.) and the Administration (e.g., other executive departments, White House, OMB, CEQ, CEA, RARG), or that the program will be acceptable to interest groups.

9. Overall Rating of Program - relative to base program, how "good" is this program.

$$\begin{array}{l}\text{Overall}\\ \text{rating for}\\ \text{policy n}\end{array} = \left\{\left[\left(\begin{array}{l}\text{Mean rating}\\ \text{on Capacity}\\ \text{to Countervail}\\ \text{for policy n}\end{array}\right)^{1.0} \times \left(\begin{array}{l}\text{Mean Rating}\\ \text{on Private}\\ \text{Costs for}\\ \text{policy n}\end{array}\right)^{0.1} \times \ldots \times \left(\begin{array}{l}\text{Mean rating}\\ \text{on Other}\\ \text{Side Effects}\\ \text{for policy n}\end{array}\right)^{0.51}\right]\right\}^{\frac{1}{4.54}}$$

The group weighting factor for each criterion was taken to be the geometric mean of all of the judgments of that factor by the six raters. The weighting factors are:

Criterion	Weight
Capacity to Countervail	1.0
Private Cost	0.1
Public Cost	0.9
Administrative Feasibility	1.0
Time to Implement	0.28
Support TSCA Aims	0.75
Other Side Effects	0.51

The group agreed that the total cost and the capacity to countervail of a policy option should be weighted equally. Thus, the sum of the weights of private and public costs should equal 1.0. For the anchor policy, however, private costs are small compared with public costs. Consequently, the relative public costs of other policies, which account for more of the total cost on an absolute basis, are weighted more heavily. This explains why public and private costs, which the group felt should be weighted equally in principle, were ultimately weighted 0.9 and 0.1 respectively, in the model.

The model was used to calculate an overall rating for each option based on only the first seven criteria. It should be noted that the model does not take into consideration ratings on criterion 8, political feasibility, or criterion 9, initial policy rating. Political feasibility was always treated as an independent judgment that did not influence the overall rating of the options. The initial policy rating represents an overall judgment of the rating of a policy compared with the anchor policy, made without reference to the individial criteria. Criteria 8 and 9 are considered further in chapters 6 and 8.

REFERENCES FOR CHAPTER 5

Delbecq, Andre L., Andrew H. Van de Van and David H. Gustafson, 1975, Group Techniques for Program Planning, Scott, Foresman and Co., Glenview, III.

W. Curtiss Priest, 1978, "Interactive Decision-Making Using Factors," Humanic Systems Co., Lexington, MA.

6. AN ASSESSMENT OF THE POLICY ALTERNATIVES

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The results of the assessment of the 32 policy options that are described in chapter 4 are presented in this chapter. The discussion is strongly based on an examination of the ratings and rank orderings of the various criteria developed in chapter 5. Also included are a qualitative discussion of these criteria and several checks of the consistency of the method.

The quantitative ratings and rankings presented here are only relative, therefore, small differences in rank or rating are not particularly meaningful.

6.1 Results of the Magnitude Estimation Procedure

6.1.1 Overall Rating and Rank Orders

The 32 policy alternatives are listed in table 6.1 in descending order of overall rating on the policy assessment model. These ratings represent the geometric means of the individual ratings assigned by each of the six members of the project team,* using the seven criterion model developed in chapter 5.**

The ratings range from a high of 1.212 for the top ranking policy (R, EPA dissemination of chemical information) to a low of 0.175 for the lowest ranking policy (CC, Regulatory exemptions for low risk chemicals). Figure 6.1 shows that the overall policy RATINGS vary regularly with the rank of the policies. However, there is a sharp drop

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*These six were Andrews, Frenkel, Heaton, Hill, Mitchell, and Priest.

**"Political feasibility" and "Initial rating" were not included in these scores.

Table 6.1 Results of the Policy Assessment

Rank Order	Overall Rating	Policy Number	Policy Name
1	1.212	R	EPA dissemination of chemical information - test results and/or labeling
2	1.114	EE	Generic PMN for classes of new chemicals
3	1.073	V	Government support to develop new, better test methods
4	1.061	C	Direct cost subsidy for testing/compliance costs of new chemical development via grant mechanism
5	1.003	DD	"Fast track" PMN's for safe and/or major innovations
6	0.902	W	Government support for education and training programs
7	0.817	D	Direct cost subsidy for testing/compliance costs of new chemical development via loan mechanism (or loan guarantees)
8	0.612	F	Indirect cost subsidy for testing and compliance costs via tax mechanism
9	0.562	X	Actions against existing substitutes for new chemicals
10	0.531	S	Chemical technology extension service, including dissemination of information on test and compliance needs
11	0.463	Y	Fixing time periods for regulatory actions
12	0.463	O	Establish government testing for TSCA requirements
13	0.453	FF	Improve EPA staff capability to assess impact of regulatory actions on innovation
14	0.445	AA	Regulatory exemptions for low volume, new chemicals

Table 6.1 continued

Rank Order	Overall Rating	Policy Number	Policy Name
15	0.440	BB	Regulatory exemptions for small firms
16	0.362	P	Sharing of test data with reimbursement
17	0.354	B	Direct cost subsidy for general new chemical development via loan mechanism (or loan guarantee)
18	0.353	Q	Facilitate private sector joint R&D or joint testing
19	0.332	K	Increased capital availability for new chemical development via tax changes or via SEC rules
20	0.316	T	Antitrust action to favor new, small firms in the chemical industry
21	0.288	I	Decreased taxes on sales of new chemicals
22	0.287	U	Tax adjustments to favor small firms or new entrants in the chemical industry
23	0.268	N	Reduce risk from products liability actions by establishing limits on liability
24	0.263	J	Increased capital availability for new chemical development via government supported venture capital company
25	0.239	A	Direct cost subsidy for general new chemical development via grant mechanisms
26	0.225	L	Reduce risk through government financed insurance for regulatory losses
27	0.221	M	Reduce risk through government procurement of new chemicals
28	0.219	Z	Post-market surveillance of PMN's
29	0.208	E	Indirect cost subsidy for chemical innovation generally via tax mechanism

Table 6.1 continued

Rank Order	Overall Rating	Policy Number	Policy Name
30	0.200	H	Strengthened trade secret protection by limitations on EPA authority to release information
31	0.188	G	Increased patent life for new chemicals
32	0.175	CC	Regulatory exemptions for "low risk" chemicals

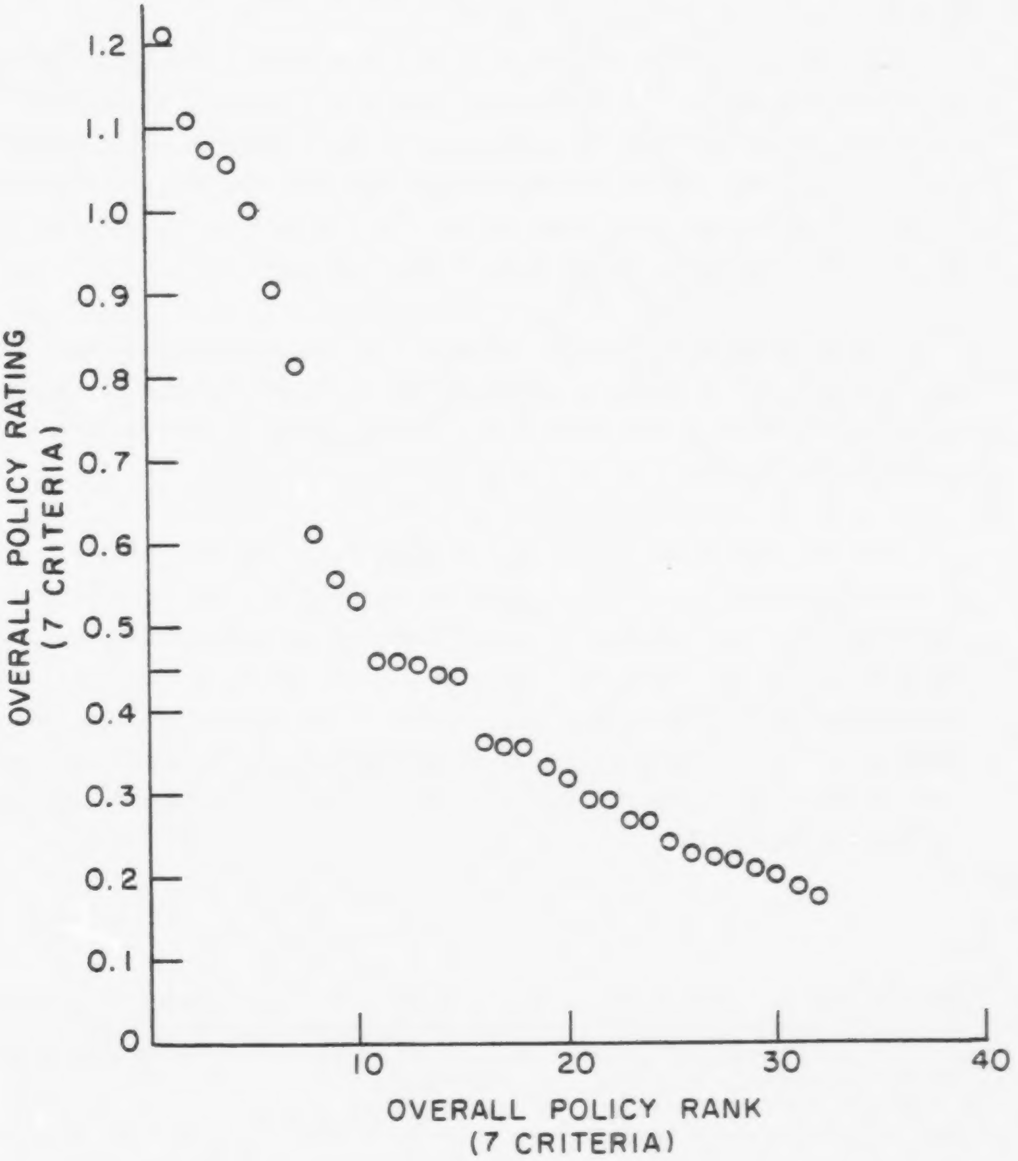

FIGURE 6.1 TREND OF OVERALL SCORE WITH RANK ORDER FOR 32 POLICIES

in ratings around the seventh ranked policy, so that policies R, EE, V, C, DD, W and D (see table 6.1 for descriptions) appear to be substantially superior to the others overall.

Very generally, the ratings can be interpreted as indicative of a measure of the ratio of effectiveness to costs. However, the overall ratings in table 6.1 have no quantitative significance as benefit/cost or effectiveness/cost ratios. Rather, they represent the overall rating on seven weighted criteria as compared with the overall rating for the anchor policy option C, which ranks number fourth.*

The relative values of the ratings have limited quantitative significance; for example, a policy rated 1.0 is not necessarily exactly twice as effective as one rated 0.5. The exactness of the ratings is uncertain for a number of reasons.

The top ranked policy options in table 6.1 represent a favorable balance of effectiveness, costs, and effects on TSCA and on various interested parties. However, the individual high ranking policies are not necessarily particularly capable of offsetting the unnecessarily restrictive impacts of TSCA on innovation. That may require adopting a somewhat lower ranking policy that is more effective, or adopting some combination of policies.** This subject is explored further in section 6.2 and in chapter 8.

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*Policy option C has an overall rating of 1.061. Its rating is greater than 1.000 because a few project members believed that this type of policy could be slightly improved over the detailed anchor policy and, could therefore be assigned a higher rating.

**This situation is analogous to that faced by a stock market investor who wishes to invest in the stock with the highest rate of return, but who may have to invest in lower return stocks as well if the number of shares of high return stock is limited.

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[**] This situation is analogous to that faced by a stock market investor who wishes to invest in the stock with the highest rate of return, but who may have to invest in lower return stocks as well if the number of shares of high return stock is limited.

TABLE 6.2 Policy Ratings on Each Criterion in Rank Order

Rank	Capacity to Countervail		Private Costs		Public Costs		Administrative Feasibility		Time to Implement		Support TSCA Goals		Other "Side Effects"		Effectiveness[a]	
Order	Rating	Policy	Rating	Policy	Rating	Policy	Rating	Policy	Rating	Policy	Rating	Policy	Rating	Policy	Rating	Policy
1	3.550	AA	4.347	E	8.849	DD	2.418	R	.963	C	5.848	R	3.732	R	1.306	AA
2	2.392	BB	4.263	K	7.023	P	1.800	N	.950	A	5.020	X	2.980	W	1.246	BB
3	1.308	EE	4.107	N	6.257	Y	1.680	V	.871	EE	2.513	V	2.655	V	1.103	C
4	1.260	C	2.667	W	6.027	N	1.648	E	.818	D	1.956	W	2.466	S	.708	EE
5	1.225	O	2.587	V	5.635	EE	.875	C	.765	R	1.308	C	1.308	FF	.494	D
6	.843	D	2.000	Y	3.942	BB	.794	W	.630	DD	1.260	DD	1.157	C	.361	V
7	.619	F	1.979	Q	3.798	R	.690	K	.607	BB	1.244	O	1.122	DD	.351	W
8	.531	L	1.979	CC	3.047	Q	.586	D	.539	B	1.000	Q	.872	D	.345	F
9	.442	W	1.919	H	2.587	FF	.585	Q	.488	F	.989	S	.858	X	.282	E
10	.442	X	1.886	S	2.418	AA	.557	F	.478	I	.849	D	.858	EE	.266	K
11	.426	B	1.743	G	2.154	H	.557	I	.464	H	.729	P	.737	T	.263	O
12	.398	I	1.648	AA	1.452	V	.541	EE	.464	AA	.649	M	.707	O	.222	I
13	.385	K	1.587	DD	1.260	Z	.521	Z	.362	V	.531	F	.497	A	.135	U
14	.368	M	1.468	BB	1.145	CC	.521	BB	.342	Y	.468	FF	.461	P	.123	DD
15	.311	DD	1.454	EE	1.103	D	.464	U	.329	U	.426	EE	.410	F	.114	L
16	.305	Y	1.260	FF	.992	F	.398	G	.326	S	.368	T	.338	U	.109	R
17	.290	U	1.214	J	.901	C	.394	DD	.301	X	.342	J	.326	B	.102	B
18	.269	T	1.193	U	.765	G	.380	H	.298	L	.217	B	.251	K	.092	H
19	.265	S	1.159	I	.765	W	.368	AA	.298	W	.208	U	.251	Y	.089	Y
20	.249	A	1.132	L	.681	X	.301	S	.290	K	.171	I	.242	J	.080	S
21	.242	H	1.013	B	.548	B	.292	Y	.259	E	.155	A	.242	I	.074	N
22	.215	V	1.000	C	.541	S	.269	FF	.242	CC	.131	K	.135	M	.065	T
23	.215	CC	.849	M	.521	T	.242	T	.215	N	.116	G	.107	L	.061	X
24	.198	J	.794	R	.464	J	.239	B	.215	Z	.112	Z	.103	G	.050	M
25	.171	E	.751	A	.414	L	.215	L	.205	J	.092	Y	.100	CC	.044	A
26	.107	FF	.739	F	.251	K	.215	O	.171	M	.071	E	.089	E	.036	Q
27	.076	P	.678	O	.180	O	.178	A	.171	FF	.044	L	.089	AA	.033	J
28	.061	Q	.586	D	.171	A	.165	J	.152	Q	.041	CC	.079	Z	.029	FF
29	.054	G	.398	Z	.163	U	.137	X	.131	O	.015	N	.056	BB	.026	Z
30	.050	Z	.231	P	.121	I	.135	M	.116	P	.012	AA	.046	N	.021	G
31	.045	R	.165	T	.109	M	.089	P	.061	G	.009	H	0.23	H	.016	CC
32	.041	N	.068	X	.069	E	.073	CC	.054	T	.008	BB	.022	Q	.007	P

[a]Effectiveness = (Capacity to Countervail) X (Administrative Feasibility)

ability to regulate unreasonable risks to health and the environment. The six with the lowest ratings (L, CC, N, AA, H and BB) can be seen as actually weakening the achievement of TSCA's primary goals, the top ten or so might significantly strengthen it, and the remainder would have only marginal effects.

6.1.3 A Consistency Check on the Overall Rankings

To test the validity of the ranking process and the assessment model, each of the six members of the project staff was asked to assign an initial overall rating to each of the policies in comparison with the anchor policy, independent of the ratings calculated on each of the separate criteria. The correlation between the rank orders of the 32 policies on these initial overall ratings and on the calculated overall ratings based on the seven criteria is shown in figure 6.2. (The initial overall ratings are the geometric means of the ratings of each staff member.)

If the initial and calculated overall rank orders had been identical, all the points in figure 6.2 would have fallen on the 45° line. As the data actually fall, they show a remarkable consistency that suggests that the assessment technique used here is valid.

6.1.4 Political Feasibility of the Policies

The project team members were each asked to rate the political feasibility of the policy options based on their judgments of the relative acceptability of the proposals to interested parties, to the various affected Executive agencies, and to Congress. These ratings are shown in table 6.3. The relationship of the rank order of the policies on the political feasibility criterion to their overall rankings is shown in figure 6.

Several points need to be made about table 6.3 and figure 6.3. The ratings on "political feasibility," which are the geometric means for six

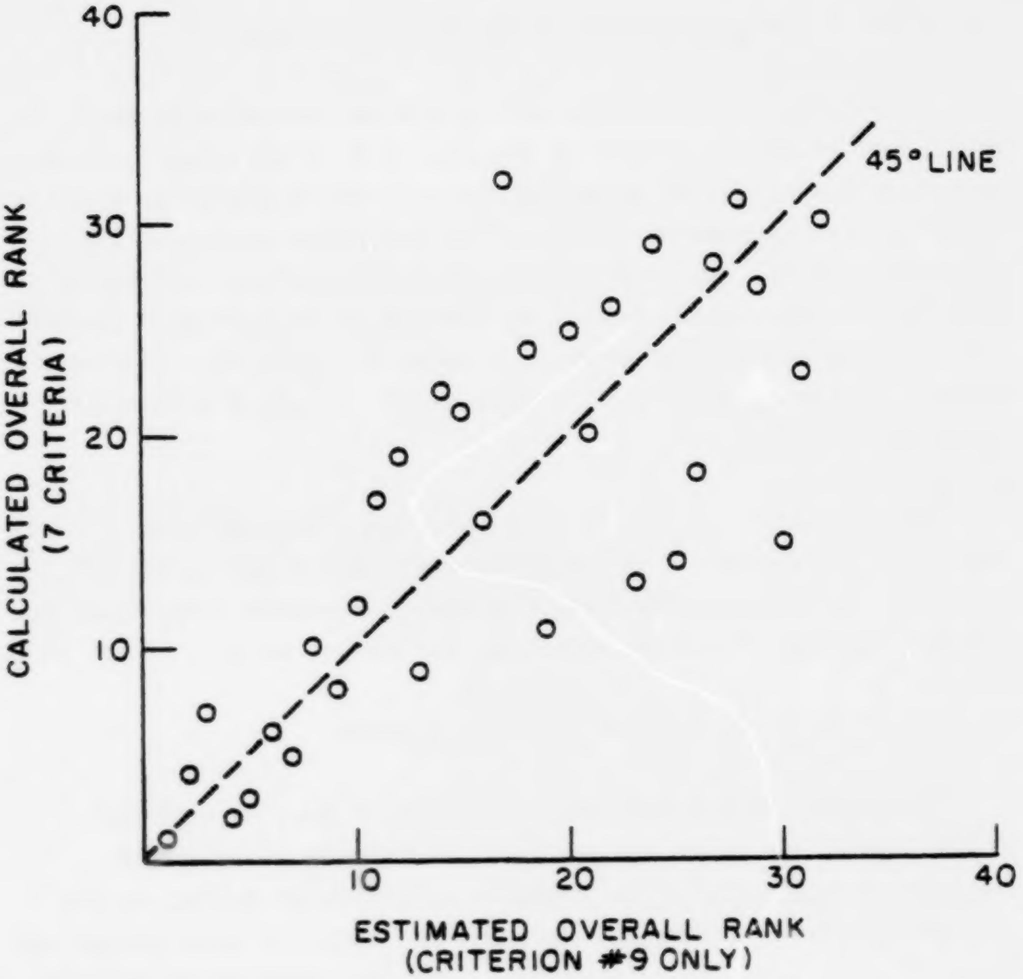

FIGURE 6.2 CORRELATION BETWEEN TWO MEASURES OF OVERALL POLICY RANKING

TABLE 6.3

Policy Ratings on the Political Feasibility Criterion

Rank	Rating	Policy
1	2.873	D
2	2.493	W
3	1.979	V
4	1.886	EE
5	1.849	R
6	1.458	DD
7	1.299	Z
8	1.238	C
9	1.103	AA
10	1.058	CC
11	.918	BB
12	.780	U
13	.645	Y
14	.607	Q
15	.442	K
16	.394	S
17	.368	B
18	.358	FF
19	.351	O
20	.301	M
21	.298	I
22	.265	L
23	.242	P
24	.147	N
25	.132	F
26	.131	X
27	.112	H
28	.100	J
29	.094	G
30	.075	E
31	.056	A
32	.013	T

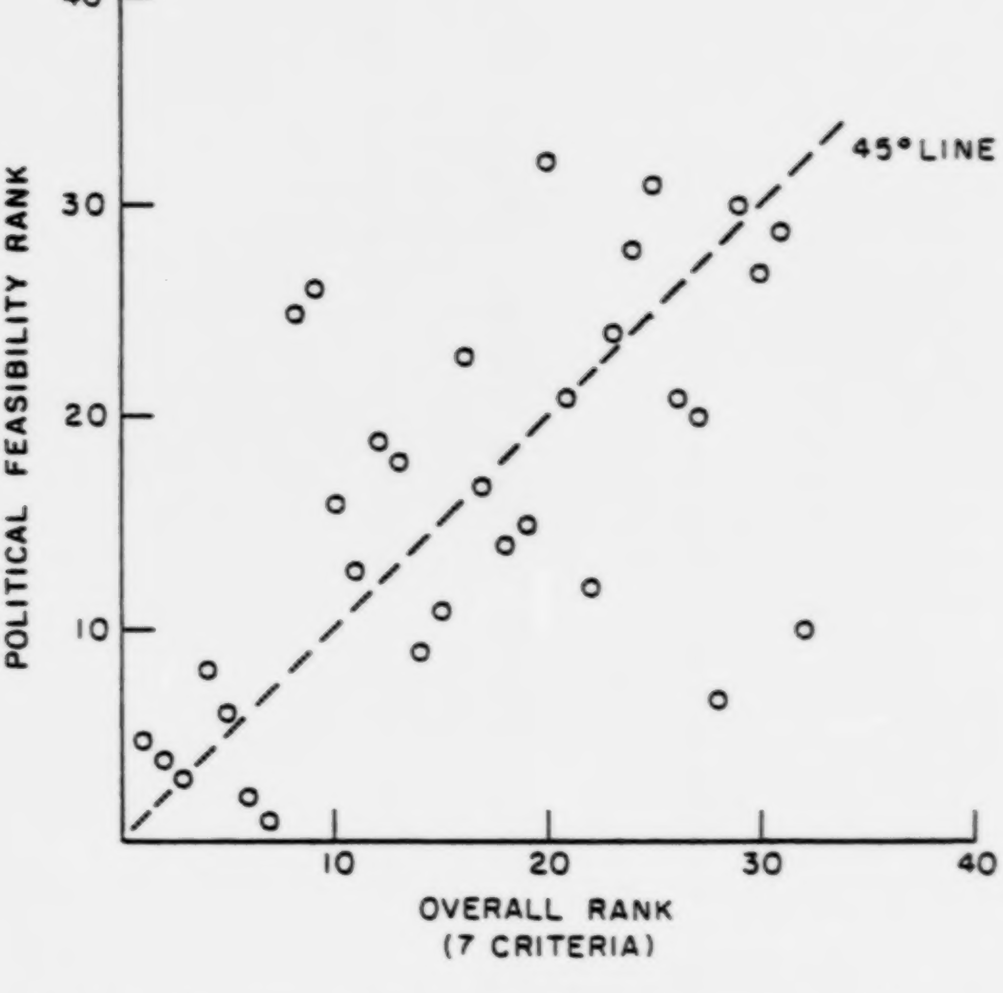

FIGURE 6.3 RELATIONSHIP OF RANK ORDERS OF POLICIES ON POLITICAL FEASIBILITY AND OVERALL RATINGS

project team members, do not represent the personal political views of the project members; rather, they are intended to reflect the best judgments by the team members of the objective political situation.

The ratings on political feasibility are separate judgments from those on which the overall ratings based on the seven criteria were calculated. Thus, the strong correlation shown in figure 6.3 can be viewed as fortuitous. The project team made no assessment of whether any particular rating or rank on "political feasibility" would render a proposal politically unacceptable.

Most importantly, figure 6.3 shows that the first seven ranking policies with respect to their overall ratings are among the first eight ranking on political feasibility. Only policy Z (post-market surveillance of PMN's), which ranks 28th overall and seventh politically, is not in this group. This lends credence to the top seven ranking policies as potentially good alternatives for action.

6.2 Discussion of the Top Seven Ranking Policies

The previous discussion has highlighted the seven highest ranking policies on an overall ratings basis as well as on the basis of political feasibility. This section examines those seven policies in greater depth.

Table 6.4 shows how each of the seven top overall policies were ranked on the seven analytic criteria, on the "effectiveness" measure discussed in section 6.1.2, and on political feasibility. Several points about this table are noteworthy.

Policies that rank highest overall do so by virtue of their weighted ratings on several criteria, so it is not necessary for them to rank high on all criteria; table 6.4 shows that they do not.

TABLE 6.4

Ranks on Individual Criteria For Seven Policies Ranked Highest Overall

Overall Policy Rank	1	2	3	4	5	6	7
Policy Identifier	R	EE	V	C	DD	W	D
Short Policy Name	Information Dissemination	Generic PMN	Better Test Methods Support	Grants for Testing Costs	PMN Fast Track	Education and Training Support	Loans for Testing Costs
Criterion							
Capacity to Countervail	31	3	22	4	15	9	6
Private Costs	24	15	5	22	13	4	28
Public Costs	7	5	12	17	1	19	15
Administrative Feasibility	1	12	3	5	17	6	8
Time to Implement	5	3	13	1	6	19	4
Support TSCA Aims	1	15	3	5	6	4	10
Other Side Effects	1	10	3	5	7	2	8
Effectiveness	16	4	6	3	14	7	5
Political Feasibility	5	4	3	8	6	2	1

The top seven policy options include those ranked 3, 4, 5, 6, 7, 14 and 16 on "effectiveness," which is the best measure of their ability to offset any unnecessarily restrictive impacts. The two most effective policies, AA and BB (exemptions for low volume new chemicals and for small firms, see table 6.2) rank lower overall (14th and 15th, see table 6.1), largely because they are ranked low on their ability to support TSCA's aims and to create side effects.

All of the top seven policy options rank relatively low on the "private cost" criterion except for policy W, education and training. However, this should not be cause for their rejection, because only the policies ranked 29th through 32nd on private costs are seen to cause any significant private costs.

Policies V, D, C, and W can be seen as having significant "public costs," with C and D being grant and loan programs that could be reasonably expensive. (See chapters 7 and 8 for a further discussion of public costs.)

Most of the top seven ranking policies rank highly on "time to implement." The exception is policy W, education and training, which would obviously require several years before results could be expected in terms of reduced costs of testing and more effective innovation.

All of the top seven policies, but one, rank in the top ten on "supportive of TSCA's aims." The exception is policy EE, (generic PMN), which can be seen as weakening the ability of EPA to assess all new chemicals adequately. Similarly, policy EE is the lowest ranking of the top seven ranking policies on "other side effects," although here it only slips to tenth place. This marginally low rank results from the somewhat enhanced potential harm to health and the environment resulting from the generic PMN. To repeat, the top seven policies overall are among the top eight on "political feasibility."

The top seven policies include policies designed to reduce the costs of new chemical development directly (C and D), to provide more information (R), to improve the technology needed for compliance (V and W),and to modify the administrative procedures for managing PMN's (DD and EE). As a group, the seven top ranking policies nicely cover several of the major categories of policies discussed in chapter 4, and thus may, as a group, offset the unnecessarily restrictive effects of TSCA on innovation at both the firm and the industry levels. (See chapter 8 for an elaboration of this point.)

6.3 Discussion of the Seven Lower Ranking Policies

As figure 6.1 shows, there is no special group of lower ranking policies upon which to focus. Furthermore, figure 6.3 does not show a good correlation between overall rank and political feasibility rank for the lower ranking policies. Therefore, it has been arbitrarily decided only to comment briefly on the seven lowest ranking policies (reference table 6.1).

The ratings of the seven lowest ranking policies on the various criteria are shown in table 6.5. (Recall that the criteria were given unequal weights in computing the overall score; see chapter 5.) This table shows that the lowest ranking policies tend to score low across the board, with one exception.

The exceptional policy is the 29th ranked policy E, (indirect cost subsidy for chemical innovation via a tax mechanism), which ranks first on "private costs", fourth on "administrative feasibility, and ninth on "effectiveness." These rankings might suggest that policy E would be a good candidate for adoption. On the other hand, it ranks as the most expensive, 32nd, on "public costs", 25th on "capacity to countervail", and 26th on both "supportive of TSCA's aims" and "other side effects." Furthermore, it was ranked quite independently as 30th on "political feasibility." Thus, policy E can be viewed overall as a very expensive,

TABLE 6.5

Ranks on Individual Criteria For
Seven Policies Ranked Lowest Overall

Overall Policy Rank	32	31	30	29	28	27	26
Policy Identifier	CC	G	H	E	Z	M	L
Short Policy Name	Exempt Low Risk Chemicals	Increase Patent Life	Strengthen Trade Secrets	Tax Subsidy for All New Chemicals	Post-Market Surveillance	Government Procurement of New Chemicals	Government Financed Insurance
Criterion							
Capacity to Countervail	23	29	21	25	30	14	8
Private Costs	8	11	9	1	29	23	19
Pulbic Costs	14	18	11	32	13	31	25
Administrative Feasibility	32	16	18	4	13	30	25
Time to Implement	22	31	11	21	24	26	18
Support TSCA Aims	28	23	31	26	24	12	27
Other Side Effects	25	24	31	26	28	22	23
Effectiveness	31	30	18	9	28	24	15
Political Feasibility	10	29	27	30	7	20	22

unpopular policy that tends not to support the aims of TSCA and is of intermediate effectiveness. Instead of attacking the unnecessarily restrictive impacts of TSCA on innovation specifically, it represents a gross subsidy to all chemical development. Finally, there are substitute policies that are similar but more carefully targeted, such as C, D, and F, which would provide grants, loans, or tax breaks for TSCA-related costs of new chemical development only, and which rank much higher overall.

6.4 Relationship of Policy Ranking to General Policy Areas

Chapter 4 categorized the 32 policy options into ten categories, as noted in table 4.1. This section reviews the relationship between the policy rankings and these categories.

Reducing the Cost of New Chemical Developmebt

These policies use grants, loans, or tax incentives to reduce the costs of new chemical development, in general (policies A, B, and E), or of the testing and compliance costs of new chemical development specifically (policies C, D, and F). The first group rank rather low overall (25, 17, and 29 respectively), and the second group rank considerably higher (4, 7,and 8 respectively). One or more of the second group are high priority possibilities for adoption.

Increasing the Financial Rewards for New Chemicals

These three policies use extended patent life (G), strengthened trade secret protection (H), and decreased taxes on sales of new chemicals (I) to increase the financial rewards for marketing new chemicals. However, they rank low overall as a group (31, 30, and 21 respectively). This occurs for G because the increased returns are expected so far into the uncertain future. Strengthening trade secret protection (H) ranks low on a number of counts: effectiveness, supportive of TSCA's aims, and other side effects. Policy I (reduced taxes on new chemical sales) ranks near the middle on most criteria, but 30th in terms of public costs, leading to a low overall rating.

Increase the Availability of Capital for New Chemicals

Policies J (government supported venture capital company) and K (increased capital through tax or SEC rules changes) rank 24th and 19th respectively. Policy J ranks low on effectiveness, public costs, and time to implement, making it generally unattractive. While policy K ranks next to the best on private costs and reasonably high on effectiveness, it ranks low on public costs and somewhat low on time to implement, and near the bottom of the middle third on other criteria. Thus, K is only of passing interest.

Reduce the Commercial Risk Associated with New Chemicals

Policies L, M and N rank at 26, 27, and 23 overall, therefore, are unlikely alternatives for adoption. Policy L, reducing risk through government financed insurance for regulatory losses, is near the middle on effectiveness, private costs, and time to implement. However, it ranks low on public costs and is seen as low on its ability to support TSCA's goals and might create undesirable side effects. Thus, it ranks low overall.

Policy M, reducing commercial risk through government procurement of new chemicals, ranks low on most criteria except for a rank of 12th on supporting TSCA's goals. This ranking probably reflects the thinking of some raters that this policy would direct government procurement toward safer substitutes. However, in most cases, government purchases of this type have been found to be inadequate in changing the civilian sector.

Policy N, reducing risk due from products liability actions by legislated limits on liability, ranks 23rd overall, despite its high scores on private and public costs and administrative feasibility. (It would rank very low on public costs as well if this program involved government in covering losses in excess of the liability limitation.) This occurs due to its low score on capacity to countervail (32nd), and because it is seen as undermining the purposes of TSCA as reflected in low scores on supporting TSCA's aims and on other side effects, since it would limit the ability of injured parties to recover damages.

Reduce the Cost of Testing

The one policy in this group, policy O, government testing for TSCA requirements, ranks 12th overall. It ranks relatively low on private costs, public costs, and administrative feasibility, despite the fact that it ranks high on capacity to countervail and on the support of TSCA's aims. It is expected to suffer from the usual problems of inefficiency in government delivery of service.

Reallocation of Cost Within the Private Sector

These two policies, P and Q, rank 16th and 18th overall, respectively. Policy P, sharing of test data with reimbursement, ranks very low on both capacity to countervail and administrative feasibility (and therefore last on effectiveness), and on private costs. It ranks near the top on public costs and on support of TSCA's goals. Thus, it is more like a low cost extension of the regulatory programs of TSCA than an aid to offsetting TSCA's unnecessarily restrictive impacts on innovation.

Policy Q, facilitating private sector joint R&D or testing, ranks very low on capacity to countervail and time to implement. It ranks last on other side effects, presumably referring to a possible substantial weakening of the antitrust laws and to a lessening of the competitive pressure that is so essential to stimulating innovation. Policy Q ranks reasonably high on private costs, public costs, and support of TSCA's goals.

Information-Based Strategies

Policies R (dissemination of information) and S (chemical technology extension service) rank 1st and 10th overall. Thus, policy R is a high priority alternative for inclusion despite its low rank on capacity to countervail. Policy S ranks near the middle on most criteria but near the top on other side effects. The latter reflects perceptions about the commercial and health-related values of such an activity that are not related to TSCA per se.

Changing Market Structure*

Policy T, ranked 20th, and policy U, ranked 22nd, would use the antitrust laws (T) or tax laws (U) to favor new and/or small firms in the chemical industry. Policy T ranks very low on private costs and time to implement and low on public costs and administrative feasibility. Since it was seen as having only an average capacity to countervail, it ranked relatively low overall as a means of offsetting the unnecessarily restrictive impacts of TSCA on innovation. Policy U (use of the tax system to favor small firms or new entrants) ranks low on public costs, high on private costs, and near the middle on all other criteria; so it is ranked relatively low overall.

Improving the Technology Necessary for Compliance

Policies V and W, which ranked third and fourth overall, would increase the supply of factors needed to improve TSCA compliance technologies. As high priority policies in the top seven, they were discussed in some detail in section 6.2.

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*These two structural policies are evaluated here only on the basis of their abilities to offset the unnecessarily restrictive impacts of TSCA on innovation. No attempt has been made to assess whether these policies might stimulate chemical innovation in general, or whether they would be cost-effective or desirable for other purposes.

Regulatory Changes

This category includes a variety of administrative actions that could be taken by EPA, or with the cooperation of Congress through changes in TSCA, which would be expected to smooth the way for new chemical devlopment and marketing. In terms of overall ranking, these fall into three groups: EE and DD; X, Y, FF, AA and BB; and Z and CC.

EE and DD, which ranked second and fifth overall, are the "generic PMN" and the "fast track." These are in the top priority list of policies, and at least the generic PMN is currently under study by EPA.

X, Y, FF, AA, and BB rank 9, 11, 13, 14, and 15 respectively. Thus, they rank just behind the top priority set of seven. Policy X, taking action against substitutes when a PMN is submitted, ranks high on some criteria but at or near the bottom on private costs and on administrative feasibility. Policy Y, fixing time periods for regulatory action, ranks high on both private and public costs, but at or below the middle on other criteria. Policy FF, improving EPA staff capability, is seen as relatively difficult to carry out (administrative feasibility and time to implement) and to have a low capacity to countervail, despite average or above ratings elsewhere. Policies AA and BB, which are regulatory exemptions for low volume, new chemicals or for small firms, are ranked highest on effectiveness and above average on private and public costs and time to implement. However. their tendency to counter the goals of TSCA directly and indirectly brings their overall rankings down to 14th and 15th.

Policies Z and CC are ranked low at 28th and 32nd respectively, but for different reasons. Policy Z, post-market surveillance of PMN's, ranks low on capacity to countervail, private costs, time to implement, support for TSCA's goals, and other side effects. Policy CC, regulatory exemptions for low risk chemicals, ranks much higher than Z on private costs, but much lower on administrative feasibility, and the same as Z on other rankings.

6.5 Conclusions Regarding the Assessment of Policy Alternatives

The use of the magnitude estimation scaling technique has yielded sets of ratings and rank orders for the 32 policy options under consideration that appear to be both internally consistent and consistent with the intuitive judgments of the team members regarding the various policies and their attributes. It is, therefore, believed that the assessments presented here should be of considerable assistance to EPA and to other interested parties in addressing the problem of the unnecessarily restrictive impacts of TSCA on technological innovation.

In section 6.2, a set of seven high ranking policies was identified and discussed. Following a discussion of financing methods for the various options in chapter 7, chapter 8 develops and analyzes a comprehensive policy opportunity based on a selection from these seven top policies.

7. FINANCING THE POLICY OPTIONS

7.1 Available Financing Modes

Any one of several different financing modes could reasonably be employed to underwrite the cost of most of the policy options discussed in chapters 4 and 6. The question of which modes are preferable is a qualitatively different matter from the question of which policy option is preferable on the basis of ability to achieve TSCA's goals. Different criteria for judging merit apply in the two situations: for example, the level of private cost is an important determinant of a program's merit, but is largely irrelevant as a public financing concern. In addition, beyond the differences in the ways they are analyzed, there are different political issues as well as a different decision process associated with the selection of a financing option. For these reasons, policy and financing options are here considered as independently as possible, recognizing, however, that at some point they must be dealt with jointly.

The first, most basic financing issue to be addressed is whether the policy in question requires new public financing. Some of the policy options require only minimal public expenditures, and in certain cases, none at all. This may be either because the policies are inherently inexpensive or because the private sector, rather than the government, bears their costs. In many instances, a policy's objective can be achieved entirely within existing agency budgets, simply by altering the agency's mandate or operating procedures. Although such policies are not likely to be without cost to society as a whole, no significant new public financing requirements are associated with them. Policies of this type include:

G. Increased patent life for new chemicals
H. Strengthened trade secret protection by limitations on EPA authority to release information
P. Sharing of test data with reimbursement

Q. Facilitating private sector joint R&D or joint testng

T. Antitrust action to favor new, small firms in the chemical industry

X. Actions against existing substitutes for new chemicals

Y. Fixing time periods for regulatory actions

Z. Post-market surveillance of PMN's

AA. Regulatory exemptions for low volume, new chemicals

BB. Regulatory exemptions for small firms

CC. Regulatory exemptions for "low risk" chemicals

DD. "Fast track" PMN's for safe and/or major innovations

EE. Generic PMN's for classes of new chemicals

Although none of the above policies requires new expenditures, some do require a realignment of personnel and emphasis within the agencies. For example, post-market surveillance would be a new EPA function. These new emphases may represent an opportunity cost to the extent that they draw resources away from valuable existing programs.

When public financing is required, two basic alternatives are available: financing via outlays from the federal budget, and financing via a variety of "off-budget" outlays. The principal options within these alternatives include:

- o budget outlays
    - reallocation of EPA discretionary funds within the agency
    - new Congressionally approved EPA programs
    - new authority and/or outlays for programs outside EPA
- o off-budget outlays
    - "tax expenditures," utilizing the Internal Revenue Code
    - new taxes
    - establishment of new off-budget financial entities
    - government assumption of contingent liabilities

The following paragraphs discuss the virtues and drawbacks of these financing options and consider how they may be applied to the policy alternatives presented in chapter 4. While no attempt has been made to

TABLE 7.1

Matching Policy and Financing Options

Policy	Budgetary Outlays			Off-Budget Outlays			
	Reallocation of Discretionary Funds	New EPA Programs	New Non-EPA Authority	Tax Expenditures	New Taxes	New Financial Entities	Contingent Liabilities
A. Grant Subsidy		X	X		X		
B. Loan Subsidy		X	X		X		
Loan Guarantee							X
C. Testing Grant		X	X		X		
D. Testing Loan		X	X		X		
Testing Loan Guarantee							X
E. General Tax Subsidy				X			
F. Testing Tax Subsidy				X			
G. Patent							
H. Trade Secret							
I. Decreased Taxes				X			
J. Venture Capital Company		X	X		X	X	
K. Increased Capital				X			
L. Insurance		X	X		X	X	X
M. Procurement			X		X		
N. Liability Limits							X
O. Government Testing		X	X		X	X	
P. Sharing Test Data							

TABLE 7.1
continued

Policy	Budgetary Outlays			Off-Budget Outlays			
	Reallocation of Discretionary Funds	New EPA Programs	New Non-EPA Authority	Tax Expenditures	New Taxes	New Financial Entities	Contingent Liabilities
Q. Joint R&D							
R. Information Dissemination	X	X					
S. Technology Extension Service		X	X		X		
T. Antitrust							
U. Tax Adjustments				X			
V. Better Tests	X	X	X		X		
W. Education	X	X	X		X		
X. Action Against Substitutes							
Y. Fixed Time Periods							
Z. Post-Market Surveillance							
AA. Low Volume Exemption							
BB. Small Firm Exemption							
CC. Low Risk Exemption							
DD. Fast-Track							
EE. Generic PMN							
FF. Improve EPA	X	X					

construct a formal set of criteria by which to judge each financing option, the following objectives are believed to be generally desirable for any financing scheme. Therefore they have been used as guidelines for this assessment:

- equity
- ease of administration
- revenue raising ability
- predictability of cost
- accountability for expenditures

7.2 Matching Policy and Financing Options

A summary of how policy options and financing options have been matched is shown in table 7.1. The entries in this table are discussed throughout this section.

7.2.1 Budget Outlays

On-budget financing is generally regarded as superior to off-budget financing because it is both more predictable and more reviewable. In addition, it fits well within existing budgetary and institutional structures. In contrast, off-budget financing often requires the establishment of new institutions. For the 32 policy options suggested in this report, the arguments for on-budget financing are especially persuasive when the public costs of new programs are small, and when they require little in the way of new institutional structures.

The option to reallocate internal EPA funds without the need to consult the Congress is available for only a few of the policies and can only be done when EPA has a large amount of funds over which it exercises independent discretion, such as for R&D support. Therefore, this financing option would be feasible only for policies such as the development of new and improved test procedures (V) or the dissemination of chemical information (R). It has the clear virtue of being quick and simple to implement. Because it is entirely internal to the agency, however, it can be criticized on the grounds that it allows programs to proceed without public debate. Reallocation of funds by EPA might also hamper other valuable agency activities whose funding is reduced.

At times, Congress may insert new line items in an agency's budget without changing its legal authority. In other circumstances, new agency initiatives will require new legislative authority. The public financing issues in these two contexts are similar. New budget line-items, however, usually tend to be of shorter duration than authority for new programs. In addition, for new line-items only the legislative appropriations process needs to be considered, as legislative authority is not an issue. Both of these avenues provide for a measure of public debate about the new program being considered, both keep new expenditures within the realm of EPA programs and both keep the expenditures visible as part of the federal budget. Policies that could be financed as new line items in the EPA budget or as newly authorized EPA programs include:

A. Direct cost subsidy for new chemical development, in general, via a grant mechanism

B. Direct cost subsidy for new chemical development, in general, via a loan mechanism (or loan guarantee)

C. Direct cost subsidy for testing/compliance of new chemical development via a grant mechanism

D. Direct cost subsidy for testing/compliance costs of new chemical development via a loan mechanism (or loan guarantee)

O. Establish government testing for TSCA requirements

R. EPA dissemination of chemical information - test results and/or labeling

V. Government support to develop new, better test methods

W. Government support for education and training programs

FF. Improve EPA staff capability to assess the impacts of regulatory actions on innovation

While policies A and B could be kept within EPA, they have the potential to become very large. In this case, they might be located elsewhere, perhaps in a new agency or in another agency whose existing mission is more closely tied to their goals, such as the National Science Foundation (NSF). On the other hand, there is a much stronger reason to keep policies C and D within EPA, since they are so closely related to its regulatory programs. Policy O necessitates a new government or quasi-public entity, which may or may not be attached to the EPA budget. Policies V and W may be inside or outside of EPA, or both. For example, existing versions of these policies now are housed in EPA, the National Institutes of Health (NIH), and NSF, among others. Lastly, policies R and FF must be implemented by EPA.

Financing these new policies outside EPA would require discussion of changes in other agencies. This approach to financing an option would also divorce its implementation from EPA's mission to some extent; a strategy more appropriate in certain cases than in others. The following policies might reasonably be implemented outside EPA:

A. Direct cost subsidy for new chemical development, in general, via grant mechanism

B. Direct cost subsidy for new chemical development, in general, via a loan mechanism (or loan guarantee)

J. Increased capital availability for new chemical development, via a government supported venture capital company

M. Reduce risk through government procurement of new chemicals.

O. Establish government testing for TSCA requirements

S. Chemical technology extension service, including dissemination of information on test and compliance needs

V. Government support to develop new, better test methods

W. Government support for education and training programs

Because policies A and B are likely to be rather large and not closely related to EPA's mission, there is a valid argument for their location elsewhere. An even stronger argument can be made for policy J, because EPA has no expertise in providing venture capital. Policy M would fall naturally within the authority of the General Services Administration (GSA), not EPA. Policies O and S would involve the government in substantial, new functions, and they may be more successful if implemented outside EPA. Moreover, the confidence that private sector participants would have in the independence of these programs might be reduced if they were attached to EPA. As mentioned above, funds for activities similar to policy option V already exist in EPA and other environmentally-oriented agencies. Additional funding could be added to provide for the education and training options contained in option W. However, other existing agencies, such as NSF, may find such programs more consistent with their existing missions than would EPA. This would especially be the case if education and training programs become large.

7.2.2 Off-Budget Financing

Although off-budget financing is generally regarded as an inferior option, it is appropriate in certain circumstances, such as when a program requires a new institutional home, when it can be financially self-sustaining, or when it involves a tax expenditure.

Tax expenditures are appropriate for the following policies:

E. Indirect cost subsidy for chemical innovation, in general, via a tax mechanism
F. Indirect cost subsidy for testing and compliance costs via a tax mechanism
I. Decreased taxes on the sales of new chemicals
K. Increased capital availability for new chemical development via changes in the tax code or in SEC rules
U. Tax adjustments to favor small firms or new entrants in the chemical industry

In general, tax expenditures are rather easy to administer and do not require new bureaucratic programs. While new tax laws often spawn considerable litigation, settlement of the legal questions usually results in a predictable set of rules. On the other hand, however, it is difficult to predict the size of tax expenditure programs. Furthermore, it is often quite difficult even to estimate the size of the resulting revenue loss to the Treasury, which can be large. Policies E, I, K, and

U would all be expected to result in substantial revenue losses. Policy F would be much less costly. Because tax expenditures are difficult to measure, they have the tendency to persist over many years without public scrutiny. Tax expenditures should therefore be considered carefully before enactment - as indeed they usually are. It is also noteworthy that the debate about the enactment of tax expenditures necessarily involves the Department of the Treasury and other proponents of the principle of tax neutrality.

Another off-budget financing option is to enact a new tax, keyed to chemical production. This could be levied in proportion to the physical production volume or to sales dollars. (In addition, the tax level might depend on the toxicity of the chemical in question. This strategy, however, presents formidable administrative difficulties and is unlikely to be successful.) The revenues from such a tax could be applied to finance the cost of a number of the policies including:

A. Direct cost subsidy for new chemical development, in general, via a grant mechanism

B. Direct cost subsidy for new chemical development, in general, via a loan mechanism (or loan guarantee)

C. Direct cost subsidy for testing/compliance of new chemical development via a grant mechanism

D. Direct cost subsidy for testing/compliance costs of new chemical development via a loan mechanism (or loan guarantee)

J. Increased capital availability for new chemical development via government supported venture capital company

L. Reduce risk through government financed insurance for regulatory losses

M. Reduce risk through government procurement of new chemicals

O. Establish government testing for TSCA requirements

S. Chemical technology extension service, including dissemination of information on test and compliance needs

V. Government support to develop new, better test methods

W. Government support for education and training programs

FF. Improve EPA staff capability to assess the impact of regulatory actions on innovation

In considering financing with a special tax on chemicals, the difficulties encountered in enacting any new tax should be kept in mind. These are both logical - i.e., policy design - and political. (The current, lengthy debate about the financing of the "Superfund" for clean up of hazardous waste sites illustrates this problem.) As mentioned above, tax policies are usually very long-lived and expensive. It does not seem to be worth the difficulties involved to establish a new tax just for financing many of the small programs that have been considered in this study. While new taxes are frequently advocated as a means of correcting for market failures, a chemical production sales tax would not efficiently do so, unless more hazardous chemicals were taxed at a higher rate.

A third off-budget financing option is to establish a new financial entity such as a public or quasi-public corporation that could become self-financing after an initial infusion of public monies. A new entity might appropriately implement the following policies:

J. Increased capital availability for new chemical development via a government supported venture capital company

L. Reduce risk through government financed insurance for regulatory losses.

O. Establish government testing for TSCA requirements

S. Chemical technology extension service, including dissemination of information on test and compliance needs

Policies J and L would include functions similar to those undertaken by existing private firms, so it is reasonable to expect that they could become self-sustaining. They could be operated on a non-profit basis, re-investing revenues in program opportunities rather than distributing dividends to shareholders. The same possibility exists for policy O, although more government subsidy would probably be required due to the nature of the activity. Policy S is an unlikely alternative for a self-sustaining new entity because it probably could not charge for its services and would need continual public support.

The last off-budget possibility is government assumption of contingent liabilities, which could be appropriate for these options:

B. Direct cost subsidy for new chemical development, in general, via a loan mechanism (or loan guarantee)

D. Direct cost subsidy for testing/compliance costs of new chemical development via a loan mechanism (or loan guarantee)

L. Reduce risk through government financed insurance for regulatory losses

N. Reduce risk in products liability actions by establishing limits on liability

Although government assumption of liability requires virtually no new commitments of funds, it has the potential to expand into very large expenditures. For example, government assumption of damage liability can create a large, never-ending drain on the Treasury if there are numerous damage suits. Accordingly, a major difficulty with this kind of financing is that it has a low predictability.

8. A COMPREHENSIVE PROGRAM OPPORTUNITY

Previous chapters have described, analyzed, and assessed 32 policy options that could be considered for offsetting the unnecessarily restrictive impacts of TSCA on technological innovation. This chapter focuses on the top seven ranking options identified in chapter 6, and builds a comprehensive program on them. Consideration is given to possible overlaps and conflicts among the program elements.

8.1 The Top Seven Policy Options

The seven highest ranking policies are identified in chapter 6, and discussed in detail in section 6.2. Certain of their aspects are shown in table 8.1, where these policies are listed in the order of their descending overall rank. These top policies are:

1. (R) EPA dissemination of chemical information - test results and/or labeling
2. (EE) Generic PMN for classes of new chemicals
3. (V) Government support to develop new, better test methods
4. (C) Direct cost subsidy for testing/compliance costs of new chemical development via a grant mechanism
5. (DD) "Fast track" PMN's for safe and/or major innovations
6. (W) Government support for education and training programs
7. (D) Direct cost subsidy for testing/compliance costs of new chemical development via a loan mechanism (or loan guarantee)

Two of these policies, C and D, are from the category, "Reducing the Cost of New Chemical Development." They are almost equivalent, with the grant program appearing preferable in most respects. (See table 8.2, which is table 6.4 reproduced here for convenience.) If designed as discussed below and in chapter 4, either of these policies would be particularly helpful to small firms and new entrants. There is no reason, however, to adopt both of these approaches.

TABLE 8.1

Some Aspects of the Top Seven Policy Options

Rank	Option	Mode of Action	Industry Segment Affected	Overlap or Conflicts	Legislative Action Needed	Estimated Annual Cost*(million dollars)	Financing Options	Status
1	R- Information Dissemination	Improves demand for safer chemicals and offsets TSCA bias in favor of existing products	All	Complements other options	None	0.1-1	Reallocation of agency funds	None
2	EE- Generic PMN	Approves PMN's for certain classes of chemicals, perhaps in advance	Highly specialized custom producers of generally safe products	Complements other options	None	0.1-1	None needed	Under consideration by EPA
3	V- Government support for test method development	Reduces testing costs	All	Complements other options	Appropriation	1-10	Appropriation increase	Underway in several agencies
4	C- Grants to offset testing and compliance costs	Offsets costs	Small firms and new entrants more than others	Overlaps policy D	Authorization and appropriation	1-10	New budget authority, perhaps funded by new tax	None
5	DD- Fast track for safer or major innovations	Reduces regulatory delay	Products that meet major social needs	Complements other options	None	0.1-1	None needed	None
6	W- Government support for education and training	Reduces testing and compliance costs	All	Complements other options	Authorization and appropriation	1-10	New budget authority	Similar efforts by OSHA
7	D- Loans to offset testing and compliance costs	Offsets costs	Small firms and new entrants favored	Overlaps policy C	Authorization and appropriation	1-10	New budget authority or revolving fund, perhaps funded by new tax	None

*Order of magnitude range of public budget costs

TABLE 8 .2

Ranks on Individual Criteria For Seven Policies Ranked Highest Overall

Overall Policy Rank	1	2	3	4	5	6	7
Policy Identifier	R	EE	V	C	DD	W	D
Short Policy Name	Information Dissemination	Generic PMN	Better Test Methods Support	Grants for Testing Costs	PMN Fast Track	Education and Training Support	Loans for Testing Costs
Criterion							
Capacity to Countervail	31	3	22	4	15	9	6
Private Costs	24	15	5	22	13	4	28
Public Costs	7	5	12	17	1	19	15
Administrative Feasibility	1	12	3	5	17	6	8
Time to Implement	5	3	13	1	6	19	4
Support TSCA Aims	1	15	3	5	6	4	10
Other Side Effects	1	10	3	5	7	2	3
Effectiveness	16	4	6	3	14	7	5
Political Feasibility	5	4	3	8	6	2	1

Source: Same as table 6.4

Two other policies, DD and EE, are changes in the administration of the regulatory process under current law. They are complementary programs, designed to address somewhat different issues. The generic PMN, policy EE, recognizes that certain classes of chemicals are very similar, and can reasonably be reviewed as a group, perhaps even including contingent clearance of future developments in the class, subject to certain procedural requirements. This option, which is currently under consideration at EPA, would address the problems of highly specialized chemical producers. The "fast track," policy DD, recognizes the additional public interest in the rapid processing of PMN's for safer or major innovations. It addresses all parts of the industry, with a bias toward new products that meet major social needs; i.e., safe substitutes, major innovations, or other criteria.

Policy R, information dissemination, is designed to improve the market demand for safer new chemicals and thereby offset the commerical bias that TSCA creates in favor of chemicals already on the market. It would favor innovative firms throughout the industry and could complement the other policies.

Policies V and W are designed to improve the technology for compliance with TSCA and ultimately to reduce the costs of compliance. Government is already devoting substantial funds to developing new, improved test methods, so option V is essentially already in place. Government support for education and training programs, policy W, could help meet the current high demand for professionals and technicians for industry and for testing laboratories, which would help all segments of the industry.

8.2 Discussion of the Comprehensive Program

It is suggested that EPA consider a comprehensive program to offset the unnecessarily restrictive impacts of TSCA on technological innovation. The program would include six of the top seven policy options; R, EE, V, DD, W, and either C or D. The characteristics, details, advantages, and disadvantages of each policy option are discussed in chapters 4 and 6. Chapter 7 discusses financing options for each program option, and notes that some of the programs might be administered by agencies other than EPA. The issue of interagency cooperation has been addressed only as part of the "political feasibility" criterion used in chapter 6.

It is necessary to consider more than one policy in a comprehensive program because no single policy is expected to be able to offset all the unnecessarily restrictive impacts of TSCA on innovation. There is no analytic way to determine how much, or how many programs would be sufficient. However, a package of six policy elements, appropriately designed, should go a long way toward offsetting these effects at reasonable cost while supporting TSCA's primary goal to prevent unreasonable risk of injury.

Policy V, support for test method development, represents only a commitment to maintain or expand on-going activities in EPA and elsewhere. It needs little further attention here.

Other than the overlap between policies C and D, all the policies in the comprehensive program would complement each other in terms of mode and locus of action and in terms of their administration by EPA or another agency.

If six of the policies were adopted, the total budget costs could be expected to be in the range of $3 to $30 million per year. A comprehensive program involving relatively limited commitment to the more costly elements (policies C, D, W, or V) could cost in the neighborhood of $7 million per year, with about $2 million per year for each element.

An experimental or trial program could be implemented at less expense and with a lower chance of disrupting the regulatory process. However, it will be difficult to evaluate an experimental program's effectiveness in view of the uncertainty in the rate of chemical innovation, with or without TSCA or the offsetting programs, as discussed in chapter 3.

8.3 Conclusion

A comprehensive program to offset the unnecessarily restrictive impacts of TSCA on technological innovation need not be very large, expensive, or disruptive. The analysis in this study suggests that very expensive programs such as grants or tax incentives for all chemical innovation in general are neither necessary, nor cost-effective. Furthermore, this analysis has shown that in order to address unnecessarily restrictive impacts of TSCA on technological innovation it is not necessary to consider programs such as regulatory exemptions for new, small volume chemicals, for low-risk chemicals, or for small firms that would seriously compromise EPA's efforts under TSCA to protect human health and the environment from unreasonable risk of injury and disease.

APPENDIX A:
THE CHEMICAL INDUSTRY, WELFARE ECONOMICS AND GOVERNMENT ACTIVITY

A.1. Purpose and Approach

A.1.1 Effects of Regulation

The Toxic Substances Control Act (TSCA) is likely to affect the chemical industry and the economy in general in ways that go beyond its primary purpose of reducing chemical hazards. In particular, there is concern in the chemical industry about the potential impacts of TSCA on chemical innovation arising from notification, testing-related, and regulatory costs imposed on the industry.

The nature and extent of the impacts on the chemical industry and on the economy depend on a great many factors. And, while it is clear that performing a general equilibrium economic analysis of the impacts lies beyond the state-of-the-art, the major impacts can be separately identified and explored. The purpose of this appendix is to explore the application of welfare economic concepts to an analysis of the impacts.

A.1.2 Utility of a Welfare Economic Approach

The utility of a welfare economic approach to the impacts of TSCA's requirements is threefold: 1) to systematically identify the impacts to help ensure that the appropriate, more important impacts are the focus of the overall study; 2) to identify and clarify areas of government responsibility for addressing the effects of TSCA; and 3) to better estimate the likely effects of remedial government mechanisms that might be adopted to countervail unwanted impacts of actions under TSCA.

A.1.3 The Framework and Its Limitations

A general framework was developed using classical welfare economics and was augmented using a public policy perspective. While the state-of-the-art of welfare economics provides the structure and the tools with which effects can be understood, it still has only a limited capacity to provide quantitative estimates. As Anderson (1974) has noted, measurement with the general equilibrium approach "is far from our reach because of the interactibility of practically estimating responses of all prices and quantities in an economy."

A.1.4 Separation of Expected and Unnecessarily Restrictive Effects

A crucial consideration in this framework is the separation of the cost-benefit consideration of regulation from the consideration of the internalization of external economies. Specifically, the intent of action under the TSCA is to internalize external costs such as those for future ill health. It is expected that these newly internalized costs will reduce consumption of chemicals in relation to other goods as higher prices must be charged for them. This is an expected effect of regulation. What remains is the question of whether there are any short-run or long-run unnecessarily restrictive impacts of TSCA on the industry that the government might decide to attempt to ameliorate.

A.1.5 Use of the Welfare Economic Framework to Trace Effects of Countervailing Programs

Once remedial mechanisms are identified it is necessary to trace the incidence of their economic impacts. For example, if input factor supply elasticities are sufficiently low, a subsidy might be passed back as increased rent to the owner of a basic material. While this might be the desired incidence for the subsidy, it may not be what was anticipated. Only when the remedial mechanism countervails with the same incidence as the regulatory costs can success be assured.

A.2. Fundamental Reasons for Government Responsibility and Intervention

In our market-based economy, the rationales for government intervention relate to the existence of market distortions, market failure, and distributional inequities. Public sector resource allocation is economically justified when the value of the public sector goods exceeds their opportunity cost; that is, the value of alternative private sector production that would employ the same resources. Furthermore, when allocative efficiency can be improved by government intervention such that the benefits more than offset the costs of intervention, government action may be called for. Finally, when the distribution of wealth, goods, and other valued items is "improper" on equity grounds it may be government's responsibility to intervene.

A.2.1 External Economies and Diseconomies

There are various situations in which the market does not operate optimally. One common circumstance is the existence of external economies. Negative externalities exist when the consumption of some good is accompanied by a detrimental impact on the welfare of others that is not captured in the market price for the good. For example, the cost of the health impacts of toxic substances on workers is not fully captured in the price of the goods they produce. The result is an overproduction of the good and a misallocation of scarce resources. Positive externalities are also common. A person who paints his house usually cannot capture the benefit derived by others who appreciate its appearance. Such a good will generally be underproduced. Thus, in some localities, governments intervene to set standards for the appearance of the houses.

A.2.2 Distortions in the Decisions of Consumer/Producers

Market failure can also occur due to distortions in the decisions of consumers or producers. For example, consumers may lack information about the value of flood insurance and underconsume it. The federal government provides subsidized flood insurance to counteract this underconsumption. Also, producers may lack sufficient knowledge or may be too rigidly based in some technology to take advantage of new technologies. Government remedies in this situation include such policies as guaranteed purchases of goods that meet specifications or direct funding for pilot plants and the like.

A.2.3 Public Goods

There are situations in which producers cannot capture the benefits of basic scientific and technical information. When information is difficult to keep private, not all the benefits of R&D will accrue to the private firms that performs it, so such firms tend to underinvest in it. This is a major rationale for government support of universities for basic chemistry and the like. To the extent that testing of toxic chemicals requires a better scientific basis, government support for it may be justified.

A.2.4 Investment Risk

Producers may also underinvest in and underproduce potentially socially desirable chemicals when the magnitude of investment risk is greater than they can afford. However, this is an important consideration only when the magnitudes of risk are considerably greater than those typically facing an industry It may be that the risk from the regulation of toxic substances is greater than that commonly faced within the chemical industry. If government cannot reduce regulatory uncertainty and if these socially desirable chemicals are underproduced due to risk, there may be reason for government to assume some of the risks. However, such risk assumption is not usually economically efficient, and it should be shown that the industry does not have alternative, lower risk areas of equivalent welfare potential for development. (Ashford, Heaton, and Priest, 1979)

A.2.5 Equity Consideration of Impacts on Industry Over A Relatively Short Time Period

While longer-run effects of regulation on industry may not justify remedial action, shorter-run effects may. It would be unfair to industry to force the internalization of large external costs in a short period of time. Out of concern for the "era-period" distributional consequences of regulation for industry, government may wish to subsidize industry at least during a transition period. (Government might wish to recoup some of the subsidy by taxing the industry at a higher rate over some long time period.)

A.2.6 Indivisibilities

Another instance of market failure and underinvestment occurs for very low volume goods. The marginal cost curve of production rises not only from increasing production with fixed assets but also for decreasing levels of production at low volume where a good may not be produced due to problems of input factor indivisibility. Since all large volume chemicals often start as low volume chemicals, society might be deprived of socially desirable goods if additional start-up costs are added by regulation or other causes. The role of capital, and in particular venture capital, is to support the production of a new product until its price covers average costs. In general, the market should adjust to added fixed costs and no negative welfare impact would result; however, if it were shown that changes in the availability of investment capital are sluggish, transitional investment capital from the government could be justified until the money market adjusted to the new situation.

A.2.7 Monopolistic Pricing Behavior

For industries such as utilities that face decreasing costs of production, government intenvention is required to prevent monopoly profits. It can be shown that a monopolist can price a good higher than is socially desirable, and that the good will be underproduced. Price regulation is then justified, in which the government sets prices at levels equal to average costs plus some level of return for investors.* For some industries such as the chemical industry, oligopolies are common for the production of many goods. Price regulation is not usually possible in the case of ologopolies but antitrust regulation in the form of penalties and criminal sanctions is often used to reduce collusion between "rival" firms.**

A.2.8 Comparative Trade Advantages

Another area where positive externalities exist and government intervention may be warranted is international trade. The implications of a trade deficit for the national economy may warrant government supports to improve our "comparative trade advantage" beyond that which the private market would provide. Also, because innovation is integrally tied to productivity, and productivity is directly linked to the standard of living, government support of means to increase innovation may also be justified. These issues are further discussed in section A.8.

A.3. Nature of Low-Volume Chemicals

Low-volume chemicals are of particular concern under TSCA because testing-related costs are likely to be a larger percentage of their costs than for chemicals whose volume will grow over time. While almost every chemical was at one time a low-volume chemical, the concern here is for those that remain low-volume, or are perceived as having only a low-volume potential when first marketed.

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*This form of regulation, while meeting certain welfare goals, itself causes allocative inefficiency.

**Oligopolies are an unusual situation for government regulation for in addition to protection against collusion, government action is used not only to prevent collusion between firms, but also to protect oligopolies from each other. Thus, for trucking and railroads the ICC sets rules for entry and rates to control price wars that have been ruinous to all involved.

As long as development costs are low, chemicals can be produced haphazardly and the marketplace can be the test of final demand. However, if testing-related costs are large in comparison to other start-up costs, a different tack is required. More market research will be required if the marketplace itself cannot be used as a proving ground for chemicals.

A chemical is likely to remain a small volume chemical under two conditions: (1) the chemical does not enter the final product or does so only in trace amounts--this is the case, for example, of catalysts and solvents that are recycled, or (2) the chemical is used in a small volume product.

The welfare economic implications of these two situations are that: (1) a chemical that does not enter a final product is likely to constitute a small percentage of the costs of production and could therefore withstand a large increase in price without appreciably affecting the supply curve for the final product, and (2) a chemical used for a small volume product is likely used for unusual purposes that are often associated with a lower elasticity of demand--an increase in its price could probably be passed through to the consumer.

A.4. Nature of Chemicals Relative to Other Goods

In understanding the welfare impacts of increased costs it is necessary to examine the cross-elasticities among chemicals and between chemicals and other goods.

A.4.1 Possible Cross-Elasticities Between New and Existing Chemicals

It is important to distinguish between existing chemicals and new chemicals. It is asserted here that high cross-elasticities would generally exist between existing chemicals and new chemicals. Therefore, the price of a new chemical is important in its ability to capture sales for existing ones. This suggests that where TSCA requirements are more costly for new chemicals than existing chemicals, the number of new chemicals entering the market would be greatly diminished. Whether this has a negative impact on welfare is not immediately obvious. It is argued below that a policy that affects new chemicals disproportionately will have a net negative impact on welfare for two reasons: new chemicals would have a positive income effect and therefore a positive impact on the standard of living and, new chemicals may be needed to displace existing, more dangerous chemicals.*

A.4.2 Possible Cross-Elasticities Between Chemical Goods and Other Goods

The cross-elasticities between chemicals (and materials) and all other goods are low. This is because consumers are more inclined to substitute one chemical for another than for a non-chemical good. For example, latex paint might substitute for an oil-based paint as prices change, but paint is less likely to be substituted for by going to the movies, when prices change. The welfare implications are that a greater proportion of test-related costs, if they evenly affect the entire chemical industry, will be passed through to the consumer than if they affect only certain chemicals.

A.5. Nature and Extent of TSCA Impacts

A.5.1 Costs Due to TSCA

Chemical testing and notification requirements raise the cost of introducing a new chemical and thus raise its selling price. Also, direct and indirect effects of TSCA may increase the number of tests of existing chemicals and add to their costs. These costs are viewed by the firm primarily as fixed costs that are generally offset by a firm's income across all of its sales.

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*To the extent that new chemicals are riskier than existing chemicals there could be positive welfare effects disproportionately affecting new chemical production.

The effects of TSCA on an individual firm will depend on the firm's size, its mix of new products and existing products, and TSCA's general impact on new versus existing chemicals. It is assumed that the additional costs associated with new chemicals, as a result of TSCA, will be greater than those for existing chemicals by at least 1) the cost of notification plus 2) the additional testing required by the greater uncertainties associated with new, unfamiliar chemicals versus existing, better understood ones.*

A.5.2 Relation to Firm Size

TSCA impacts will be greater for small firms if there are economies of scale for testing-related costs. It is generally claimed that large firms have easier access to capital, thus can more easily respond to testing-related requirements. As an alternative, if smaller firms could contract for testing with outside testing laboratories that achieve the same efficiency as those in large chemical companies, the size advantage of large firms would be greatly reduced. While there may be additional delays and secrecy problems associated with the use of an outside laboratory, these costs may not outweigh the benefits achieved through economies of scale.

A.5.3 Relation to the More "Innovative" Firm

The degree to which a firm's revenues are derived from the introduction of new chemicals is of more serious concern in an analysis of TSCA. If all firms developed the same percentage of new chemicals there would be no no differential impacts. However, firms that derive a greater than average proportion of their revenues fom new chemicals could be seriously affected if the demand for their new products is not highly elastic.

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*Some might question the assumption that existing chemicals are better understood.

A.5.4 Possible Excessive Exits or Mergers -- Concentration Effects

Long run effects of TSCA could be serious if firms that emphasize introduction of new chemicals are responsible for the overall pattern of innovation in the chemical industry. If TSCA were to cause these firms to exit from the market, the long-run impacts could be great. In contrast, if the economic impact of the requirements is smaller and these firms are not forced to exit, or if the innovative potential of the industry is associated primarily with firms that are diversified between existing chemical production and the introduction of new entities, long-run impacts may be low.

If diversified firms find it to their competitive advantage to acquire firms that produce high percentages of new chemicals, market restructuring would occur. The welfare effects of these actions would then stem from increased industry concentration. Greater industry concentration leads to a more oligopolist market and attendant market distortions. Consumer prices will rise as more monopolistic marketing occurs. Also, the indirect effects of industry concentration on productivity, innovation, and quality of working life are generally believed to be negative. Smaller firms, in general, are often found to contribute a disproportionately higher number of innovations within an industry. Also, the "small is beautiful" literature suggests that quality of working life decreases as firm size increases for various structural/ sociological reasons.

A.6. Demand/Supply Dynamics

TSCA can be viewed as adding to the fixed and variable costs of producing chemical goods.* Since the increased value of chemicals -- lower risk to health -- is unlikely to be substantially captured in their selling prices, the demand for them will remain constant in the short-run.

A.6.1 Cost-Sharing Provision of TSCA

The "cost sharing" provisions of TSCA are designed to allow the spreading of testing costs over all firms that produce the chemical for which testing is required.** Thus, production volume may be important since fixed testing costs that are spread out over many units of production raise average fixed costs only slightly.

A.6.2 Single Firm Production

Consider the case of a low volume chemical that is produced by a single firm. Such a firm faces the demand schedule shown in figure A.1 and is unable to influence the price at which its product is sold. The fixed costs of testing for low volume chemicals can add substantially to the average costs of production.

The firm will make a profit by producing any quantity between Q1 and Q2 and will, in fact, produce the profit maximizing quantity (as in the case of a monopoly, price does not necessarily equal marginal cost at the profit maximizing point). When fixed costs are increased by testing costs for example, the average cost curve will move to AC' as in figure A.2.

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*Costs due to TSCA need not all be fixed costs. As production rises, the chemical is likely to cause greater exposure and additional testing costs are likely.

**It should be noted that this provision provides for reimbursement of testing related costs for the successful chemical but not necessarily for all the unsuccessful chemicals a firm considers. Thus, reimbursement may actually defray only a small part of the total costs to the firm.

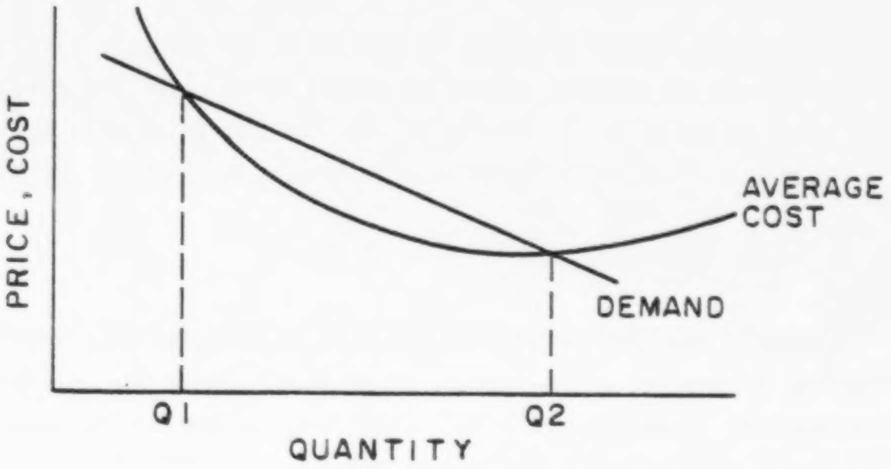

FIGURE A.1 PRODUCTION ECONOMICS FOR A SINGLE FIRM

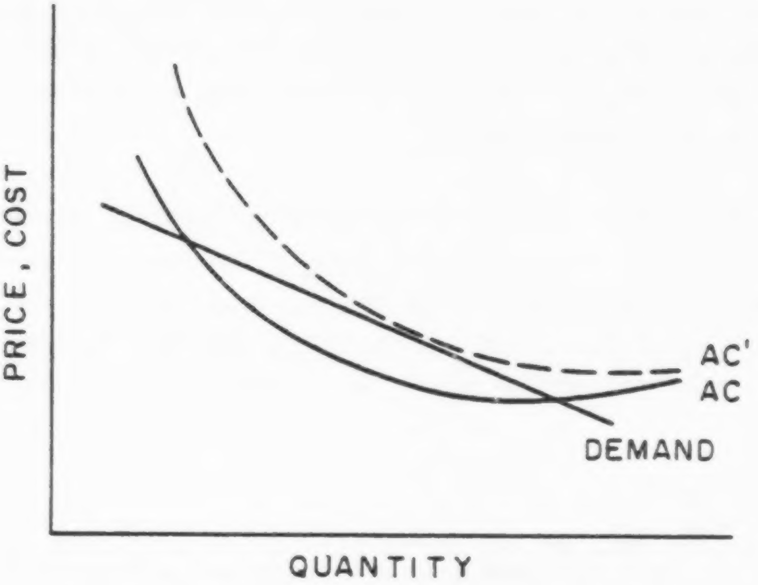

FIGURE A.2 EFFECT OF TESTING COSTS ON SINGLE FIRM PRODUCTION ECONOMICS

In deciding whether to produce a new chemical a firm will consider the testing costs as a fixed cost (albeit a one-time cost), and will augment the average cost curve by this amount (adjusted for the likely "life" of the chemical). Too large a testing cost may make the average cost of production too high for some chemicals, and consequently, they will not be produced. The importance of testing costs is reduced by higher expected demand, inelastic demand, longer chemical "life," and patent protection.

For an existing chemical, the decision to perform mandatory testing will be decided on the basis of the average variable costs of production. Since the costs of existing plant and equipment used in producing a chemical are sunk costs, they must be covered regardless and should not affect the decision. Testing will be performed if revenues are adequate to cover pre-existing average variable costs plus the testing costs as amortized over the remaining commercial life of the chemical.

As the sunk costs are reduced, the criterion for deciding whether to continue producing an existing chemical approaches the criterion for deciding whether to produce a new one.

A.6.3 Multi-Firm Production

For a multi-firm market the situation is more complex. Cost sharing and relatively high dollar sales volume can mean that the impact of the testing costs on per-unit production costs is likely to be small. However, for chemicals produced in moderate volume, testing costs force supply prices up, and lead to reductions in demand. The result will be a new supply/demand equilibrium at a lower quantity of production (and higher price) and the accelerated exiting of marginal, less efficient, firms from production.

A.6.4 Multi-Firm Production with Variable Cost Changes

Increasing variable costs add to the marginal cost of production and shifts the supply curve, much like a tax per unit of production acts to shift a supply curve. This situation is depicted in figure A.3. The increase due to TSCA is added vertically to the supply curve, moving it from S to S'. The quantity sold decreases and the price increases, but not by an amount equal to the added cost.

In terms of marginal analysis, the reduction in supply is caused by the fact that each firm's marginal cost is now greater at each level of output. This means that the profit maximizing position of each firm is at a lower level of output. Hence, the total market supply curve shifts upward and to the left. This is shown in figure A.4. In a competitive market, firms set the quantity such that MC=P.

A.6.5 Consumers' and Producers' Surplus

The welfare economic effects of these shifts can be traced from the changes in consumers' surplus and producers' surplus accompanying them. At an elementary level it can be said that there has been a loss to the consumer, owing to the price rise. This loss, which corresponds to the difference in consumer surplus before and after the price change, is shown in figure A.5.

The change in consumers' surplus is the area of rectangle A plus the area of triangle B. Area A depicts the situation where the good is still consumed but with less surplus to the consumer (e.g., if consumer A was willing to pay twice the price for the good at its original price, and if the price increases by 40%, consumer A is now only willing to pay 60% more than the price for the good. Thus, while the good is still consumed, the surplus diminishes). Area B depicts the loss in surplus from the quantity of the good that is no longer consumed and is the result of the drop in consumption is from Q to Q' -- here the marginal

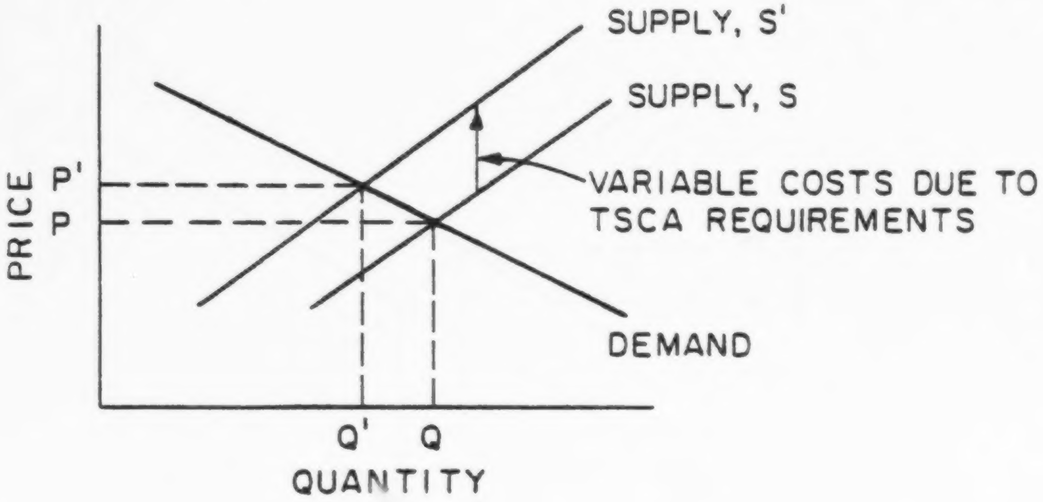
SUPPLY, S'
SUPPLY, S
VARIABLE COSTS DUE TO TSCA REQUIREMENTS
PRICE
P'
P
DEMAND
Q'
Q
QUANTITY

FIGURE A.3 IMPACT OF TSCA REQUIREMENTS ON THE SUPPLY AND PRICE OF A CHEMICAL GOOD

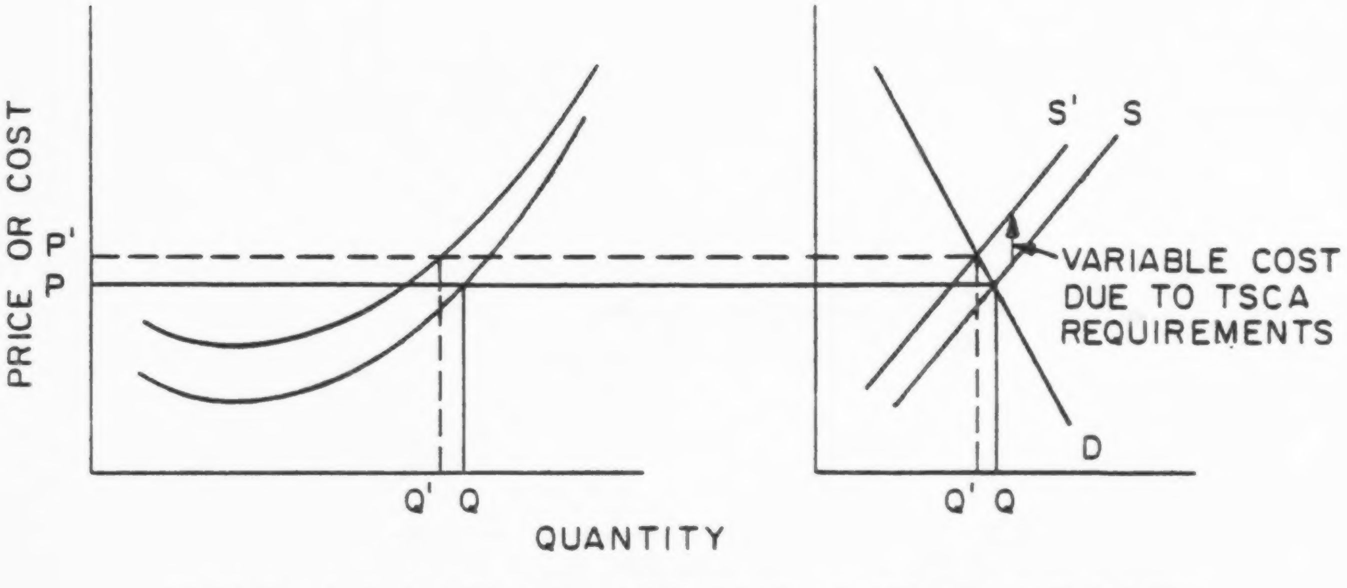
PRICE OR COST
P'
P
Q'
Q
QUANTITY
S'
S
VARIABLE COST DUE TO TSCA REQUIREMENTS
D
Q'
Q

FIGURE A.4 MARGINAL ANALYSIS OF THE SHIFT OF THE SUPPLY CURVE FOR A CHEMICAL GOOD UNDER TSCA

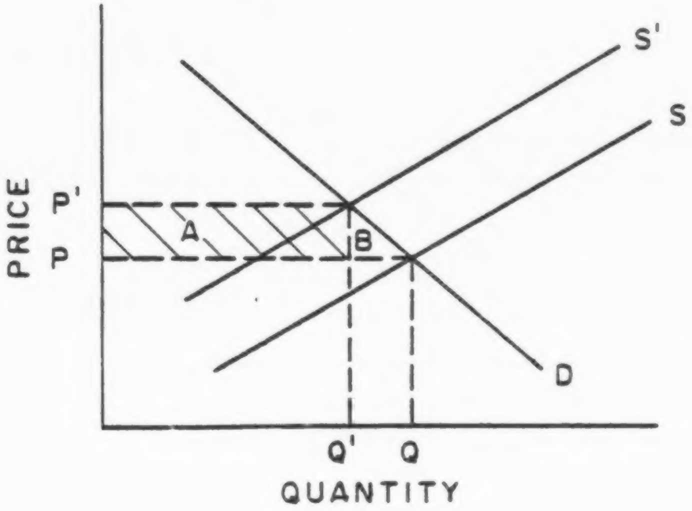
S'
S
PRICE
P'
P
A
B
D
Q'
Q
QUANTITY

FIGURE A.5 CHANGE IN CONSUMERS' SURPLUS UNDER TSCA

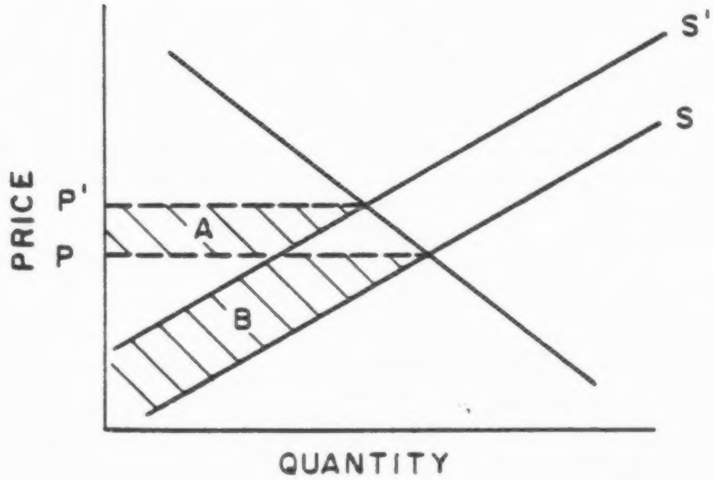
S'
S
PRICE
P'
P
A
B
QUANTITY

FIGURE A.6 SHORT-RUN CHANGE IN PRODUCERS' SURPLUS UNDER TSCA

utility of the good to the consumer was sufficiently low that the consumer substitutes other goods for the consumption of this particular good as a result of the change in price.

The loss of consumers' surplus is a real loss to consumers and a welfare economic impact. But, looked at from the other direction, it partly represents the subsidy provided by those individuals who suffered health losses before TSCA requirements were added. This is part of the welfare economic exchange that Congress has bargained for in passing TSCA, and should not be considered to be an uncompensated economic loss.

A complementary concept to consumers' surplus is producers' surplus. This is the value represented "behind" the supply curve as shown in figure A.6.

In general, the producers' surplus decreases as the fixed cost increases and as area A minus area B becomes less than zero. (The producers' surplus is the difference between the total revenue and the total cost).

The welfare interpretation of the producers' surplus is not as simple as that of the consumers' surplus. In the short-run, a decrease in producers' surplus reduces the profitability of the firm. In the long run, where there is time for firms to enter or leave a competitive industry because of changes in price and profit, the producers' surplus goes to zero. In this longer time period, the market supply curve is not the sum of the supply curves of the individual firms but rather a description of how costs in the individual firms will be affected by the entry of firms: in a competitive market, profit levels are generally fixed because of the entry and exit of firms. For example, if profitability were to increase, other firms would enter the market, increasing the supply of the product and decreasing the price of the product until profits return to "normal." (Normal profits are those levels of return on capital that are typical for the level of risk involved.)

Thus, the actual impacts of changes in producers' surplus relate more to the entry and exit of firms than to changes within any particular firm. The next section will further explore the welfare economic implication of these changes.

A.7. Microeconomic Welfare Effects

A.7.1 General Rules for Cost Pass-Forward and Pass-Back

The imposition of costs at a given point, in an economic system, is felt thoughout the system to a degree that depends on the supply and demand elasticities for the input factors and the outputs.

- for input factors -- the more inelastic the supply of an input factor, the more that costs can be passed back to the supplier of that input factor.
- for outputs -- the more inelastic the demand for outputs, the more that costs can be passed forward to consumers.
- for the producer -- the relative slopes of the producers' supply curve and the consumers' demand curve determine the proportion of costs that is passed forward to consumers.

A.7.2 Multimarket Dynamics

In a multimarket situation, where suppliers and producers are vertically integrated, recent welfare theory has shown that the concepts of consumers' surplus and producers' surplus capture the aggregate welfare effects back to the first suppliers and forward to the final consumers. Under certain conditions required for the validity of consumers' surplus measures in the final goods market and producers' surplus measures in the initial resource market, the following was found to hold:

- The area behind a general equilibrium demand curve in an intermediate market does not measure benefits to buyers in that market alone, but rather measures the sum of rents to producers selling in all higher markets (assuming no intervening market has perfectly elastic demand) plus final consumers' surplus.

- The area behind the general equilibrium supply curve in an intermediate market measures not only rents for producers selling in that market, but also rents for all producers selling in more basic markets (assuming no intervening market has perfectly elastic supply) plus those of initial resource suppliers. (Just and Hueth, 1979)

Thus, a practical approach to studying the distribution of welfare effects over all other market groups in a sector is to estimate areas behind general equilibrium supply and demand curves in the market of interest. Then welfare effects on direct market participants are separated out by subtracting areas behind ordinary supply and demand curves. Further, if appropriate data exist, the distributional aspects for other industries can also be studied by separating out the respective values-added.

A.7.3 Captive Suppliers

When the elasticity of demand for a final product is high and the elasticity of supply is low, costs will be passed back from the chemical manufacturer to the resource supplier. This is often the case with captive suppliers of major inputs. For example, the rent on cadmium or in the manufacture of paint pigments may be primarily determined by the price the final product can command in the market. Thus, added costs in production will go to reducing the rent on the cadmium ore. (If cadmium ore production is not fully captive, that is -- other producers who are not affected by cost increases keep the price up, costs cannot be passed back as easily.)

A.7.4 Worker Impacts

When the input under consideration is labor, and when labor mobility and labor supply elasticity are low, there are serious economic welfare consequences of increases in production costs. In these cases, costs will be passed back to labor in the form of lower wages and the net effect of regulation will be a negative transfer to the worker. It is generally expected that this effect will be short-run and that long-run elasticities would generally be high enough to reduce this effect.* Nonetheless, if the effect is significant it argues for government attention to reducing the impact on workers out of equity considerations.

A.7.5 Impacts Due to Reduced Producers' Surplus

Reductions in producers' surplus, as mentioned above, will in the long run cause firms to exit or discourage new firms from entering the market. These market changes result in losses due to idle capital and to unemployment. These are important welfare considerations. In some industries, such as the railroads, when changing market conditions reduced the need for workers, additional problems were caused by featherbedding and other practices that mitigated against displacing the workers. Clearly it is not economically efficient to retain unneeded labor, and thus it may be advisable to review our country's capacity to retrain and absorb displaced firms and workers that may result from added costs to chemical production through regulation.

A.7.6 Impact on Financing

A further impact of cost increases to a firm is a reduced ability to raise capital. Capital is generated internally through a firm's earnings or raised through equity issues or borrowing. The ability of a company or industry to raise capital is tied to its earnings. An increase in production costs that is not passed on reduces a firm's ability to raise capital in three ways.

First, for a chemical firm to make purchases using debt, it must put up around 20% of the purchase price. The equipment or facilities the company is purchasing can serve as collateral to the vendor, who finances the other 80% of the cost. When a chemical company must spend funds on testing-related costs, its earnings are correspondingly reduced and the ability to make such payments is reduced. The effect of this reduction is magnified five times; if the chemical firm cannot put up 20¢ it cannot receive returns on a $1.00 investment.

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*Higher elasticity will reduce the wage impacts, but the worker still bears the cost of relocating, retraining, and job searching.

The second way a cost increase impacts raising capital relates to the debt/equity ratio.* To a lender, the debt/equity ratio is a key indicator of the risk involved in extending further credit to a company. As the ratio rises (for example, because of the need to finance testing facilities) the marginal lender may decide not to lend to the company. This reduces the money available to the chemical firm for a given lending rate.

Finally, reduced earnings and equity influence the market value of a firm's stock. When the firm tries to raise capital through an equity offer, the stock process is an important factor since the price at which the new stock in tendered is closely tied to the current market price. A production cost increase that decreases earnings also decreases the stock price and thereby reduces the amount of capital the company can raise through an equity offer.

The possible decreased ability of a chemical firm to raise capital, at least over the short-run, adds to problems of stability, and more importantly, hinders the firm's ability to finance new technology with improved productivity. In response, government might be concerned about increased industry instability due to regulation, at least during a transition period, and also be concerned about the possible reduction in innovation and productivity growth over the long-run.

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*Stockholders equity is the sum of the par value of the stock, the paid-in capital (total capital raised through equity issues), and the retained earnings of the company (earnings not distributed as dividends to stockholders).

A.7.7 Positive Impacts Due to Regulation

Positive welfare effects will also accrue to the firm from testing-related requirements. Chemical firms have said that information they have gathered in the course of complying with a government regulation have contributed positively to new product development in some cases. (Ashford, Heaton and Priest, 1979; Ashford and Heaton, 1979) Klein (1979) has suggested that for some industries that are rigidly based, regulation provides an impetus to reducing industrial inertia. To the extent that positive externalities due to regulation are evident in the chemical industry, these will mitigate against cost increases and reduce the negative welfare impacts described above.

A.8. Micro-Macroeconomic Welfare Effects

Considerations of microeconomic welfare effects fail to capture the larger scale dynamics that are believed by many to be critical to the welfare of the U.S. economy. These include concerns for innovation, productivity, labor/capital ratios, inflation, and international trade advantage.

Improvements can be viewed in these micro-macroeconomic concerns as positive externalities that arise from all economic/social activities, including activities of the chemical industry. The limited resources allocated to each sector are subsequently leveraged to attain these positive micro-macroeconmic effects.

The welfare economic consideration here is estimating the benefits of these effects and determining increases or decreases in these effects caused by TSCA. Many of the components of this exercise have already been discussed in prior sections. What remains is to consider the overall sense of the effects.

A.8.1 Increased Productivity as a Significant Contribution to Social Welfare

Bourdon (1979) has traced the effects of innovation and technological change on labor productivity and compensation. Hill (1979) has traced the linkages between innovation and technological change and such social welfare measures as the quality of work and the quality of life. These studies conclude that productivity increases are accompanied by increases in the standard of living and may be a means of taming inflation. The implications of these conclusions are that the promotion of innovation is a primary means to achieve increases in social welfare.

At a welfare economic theoretical level the implications of innovation can be examined as follows. Innovation can decrease costs or increase value. By decreasing costs and holding demand constant, personal disposable income increases -- this is an income effect. With this additional income, more goods can be purchased and this is an increase in welfare. If the value of a product is increased (such as the development of a paint that wears longer or is more aesthetically pleasing), and if demand is constant, consumer surplus is increased -- this too increases the net welfare of society.

A.8.2 Should the Chemical Industry be Singled Out for Attention Vis a Vis Innovation in General?

There is no reason to prefer subsidizing one activity versus another with regard to innovation (or any of the other micro-macroecnomic effects) unless it is believed that (1) one sector of the economy offers greater leveraging advantage than another, and that (2) the market system would not naturally capture this advantage. Since innovation brings benefits to both business and society, areas of greater innovation potential will correspond in most cases with areas of industrial growth and investment. Government intervention is justified only when the positive externalities of innovation in one sector are greater than in another.

Thus, for the chemical industry, if positive externalities are identified and if these externalities are of a larger value than those associated with other sectors (per resource dollar allocated), government should preferentially intervene in the chemical industry. Furthermore, government should intervene regardless of whether TSCA imposes additional costs. One positive externality already indentified is the potential for new chemicals to replace existing, more hazardous chemicals. A negative externality associated with the chemical industry, however, is its dependence on petroleum sources and its demand for energy.

In general, if the chemical industry offers greater increases in value-added because of innovation in comparison with other pursuits, this would lend support for government intervention to increase dynamic economic welfare.

A.9. Examples of Chemical Products Illustrating Differing Market Structures

A.9.1 Factors Determining Inputs

In the preceding section the economics of TSCA-related impacts was discussed from a theoretical viewpoint. As was shown, the impacts of chemical testing requirements vary with firm size, volume of production, chemical price, and the extent to which cost increases can be passed forward to consumers or back to the suppliers of the impact.

Firm size influences the impact of TSCA requirements because small companies will, in general, not as easily be able to raise the resources or perform the testing required.

High dollar sales insure that TSCA related costs will only result in a small percentage price increase. On the other hand, low dollar sales mean that added production costs will have a proportionately larger impact on prices.

The elasticity of demand determines the extent to which cost increases can be passed on to the consumer (or intermediate user) without incurring large sale losses. High elasticity implies that there will be large sales losses if costs are passed on, while low elasticity implies the reverse.

Production requires the input of raw materials, intermediate goods, labor, and capital. When a raw material or intermediate good is used to produce one good almost exclusively, the demand for that good will in large part, determine demand for the input. If the price of the input falls as the demand for the good falls, supply price elasticity will be said to be high. If, on the other hand, the input is also used in other production processes, demand for the good will not greatly influence its price and supply elasticity will be said to be low. High supply elasticity is borne by the suppliers of inputs, while low supply elasticity implies the reverse.

A.9.2 Examples of Inputs

Any chemical product subject to TSCA regulation may be characterized by its sales volume, by the size of firm(s) engaged in its production, and by the elasticities of demand and the factor supply relevant to its sale and manufacture. While these criteria do not fully determine the likely impact of TSCA regulation, they are useful for an initial assessment.

In table A.1, each of these criteria has been decided dichotomously, resulting in 16 different industry "cases." An attempt has been made to illustrate each case with an example from the chemical industry.* The reasons for the choice of each example are discussed below.

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*There is markedly little literature on measured demand and supply elasticities. These examples were arrived at through the concensus of the staff members familiar with chemical usage and should be considered only suggestive here.

TABLE A.1 Examples of Chemicals in Various Categories

Sales Volume	Company Size	Demand Elasticity	Supply Elasticity	Example
Low	Large (highly concentrated)	High	Low	Auto Touch-Up Paint
			High	Flame Retardants
		Low	Low	Catalysts (used in production of ammonia, hydrogen and nitric acid)
			High	Enzymes
	Many small with some large (medium to unconcentrated)	High	Low	Low Volume Consumer Adhesives
			High	Exotic Non-Essential Intermediates
		Low	Low	Airplane Adhesives
			High	Exotic Essential Intermediates
High	Large	High	Low	Synthetic Rubbers for Tires
			High	Some Colored Inks
		Low	Low	Carbon Black
			High	Phosphate Fertilizers
	Many small (with some large)	High	Low	Plastic Colorants
			High	Rendering of Animal Fats
		Low	Low	Propane for Home Use
			High	Sulfuric Acid as a Waste Product

Source: CPA

Auto Touch-Up Paint - these relatively low volume paints are produced predominantly by a few medium-sized companies. The elasticity of demand for any specific product is likely to be high since substitute competitive formulations exist. The materials used in the production of these paints are generally used in larger quantities elsewhere; hence, the prices of these inputs are not likely to change much in response to changed demand from auto touch-up paint manufacturers. Products falling in this category are likely to be quite sensitive to mandated costs increases since sales are likely to fall and costs cannot be passed back to material suppliers.

Flame Retardants - flame retardants are used extensively in plastics and synthetic fibers, and some are relatively low volume. Because of the number of competing formulations, the demand for any specific flame retardant is likely to be somewhat elastic. On the other hand, the input materials used in manufacturing a flame retardant may be used almost exclusively for that purpose. It is thus possible that supply prices are fairly elastic where the input is not captively produced.

Catalysts Used in the Manufacture of Ammonia, Hydrogen, and Nitric Acid - these catalysts are produced in comparatively low sales volume but are important in the production of commodities sold in much larger volume. Consequently, demand elasticity is low while supply elasticity (for such chemicals as nickel, iron, copper, zinc, platinum, and silver) is essentially non-existent for this end use. The catalyst industry is characterized by considerable captive manufacture, with only 20 firms producing catalysts for the market.

Enzymes - enzymes are used in the preparation of meats and dairy products, in brewing, in laundry detergents, and in the preparation of tobacco, paper, textiles, leather, and other products. Relative to their cost, enzymes play an important role in the manufacture of these high volume items, and in consequence demand for them is

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likely to be inelastic (except in laundry detergents). Raw materials for enzyme production include fungi and yeast, and such meat by-products as hog and beef pancreases, stomachs, and glands. Since enzyme production may be an important market for some of these inputs, it is likely that supply price elasticity will be high (i.e., the market price for beef pancreases will be sensitive to the use of enzymes made from this input).

Low Volume Consumers

Adhesives - this group of chemical products includes lower volume adhesives placed directly on the consumer market, often for specified applications. When the intended application is not critical or when substitute formulations exist, it is likely that consumer demand for any individual product will be elastic. Because the inputs used in producing these products are also used in much higher volume elsewhere, a slight change in factor prices will result from reduced sales of a specified low volume adhesive (factor supply elasticity is low). While adhesives are also produced by large firms, this segment of the chemical industry is dominated by small and medium size manufactures.

Fragrances and Flavors - while there are only about 150 natural essential oils in commercial production there are approximately 3,000 synthetic aroma chemicals commercially available, and many of these are produced or blended by small companies. With such a wide range of chemicals available, it is likely that demand for any particular aroma chemical is high. Supply price elasticity for these low volume chemicals is likely to be low, however, as the raw inputs are also extensively used to manufacture other products. Because of the skill involved in developing and blending aromas and fragrances, small firms thrive in this area, although some larger firms produce and blend aromas for their own use.

Exotic Non-Essential Intermediates - while it is difficult to locate an example of a chemical in this category, they undoubtedly exist. Any low volume chemical intermediate for which economic substitutes exist, and which is produced from low volume inputs, would fall into this category.

Airplane Adhesives - adhesives are an important, if low volume, input in airplane construction. Because of the importance of the adhesives in maintaining structural integrity, and the strict testing required to substitute an alternate product, it is likely that there is little demand elasticity for these products. While data on the production of these adhesives could not be easily located, the adhesives industry as a whole is marked by small firms.

Exotic Essential Intermediates - essential, low volume, intermediates are chemicals used in a production process that cannot economically operate in their absence. Demand elasticity for such chemicals will be low, and if they are in turn produced from low volume chemicals, input prices will be elastic with respect to demand.

Synthetic Rubbers for Tires - synthetic rubbers are high volume chemicals produced predominantly in large plants. In the manufacture of tires, natural rubber and synthetic rubbers may be blended together. Because the price of natural rubber is now close to the price of synthetic rubber, there is some demand elasticity for the synthetic product. The raw material from which synthetic rubber is produced, petroleum, is totally inelastic in price with respect to changes in this source of demand.

Selected Colored Inks - many colored inks are high volume items with ready substitutes. They are thus likely to face considerable demand elasticity. On the other hand, some of the inputs used in manufacturing these inks may be specifically manufactured intermediates so that supply factor elasticity may be relatively high.

Carbon Black - carbon black is an essential ingredient in the manufacture of rubber tires, this application accounting for 90% of their total production. Because of the importance of carbon black in reinforcing rubber and the lack of economic substitutes, demand elasticity is low. On the other hand, because carbon black is produced from liquid or gaseous hydrocarbons, and constitutes only a minor use of these inputs, input price is insensitive to demand. All of the eight producers of this high volume chemical are large companies.

Plastic Colorants - plastics come in many colors. Because specific color is not essential in many applications, and because substitute color formation exist for some shades, demand elasticity for many specific colors is going to be high (volume may either be low or high). When raw material inputs are chemicals that are generally available, supply elasticity will be low. It should be noted that only some, not all, plastic colorants will fall in this category.

Rendering of Animal Fats - surfactants include both soaps from natural fats and detergents produced from synthetic raw materials. Detergents have replaced soap nearly everywhere except in the toilet bars market, but even here mixed soap and detergent and pure detergent bars have appeared. The first step in the process of producing soap is to render animal fat, a process that is dominated by small firms located close to the raw materials market (i.e., meat processing plants). Demand for this product, rendering animal fat, is highly demand elastic because of the alternate formulation of soap with synthetic detergents, and because other oil (e.g., soybean, coconut) can be used instead. The raw inputs for rendering oil are essentially waste products that could not find a market elsewhere. Hence, supply price is highly elastic with respect to demand by the rendering industry.

Propane for Home Use - while the bottling of propane for home use does not involve a chemmical process, this is one clearly defined (and regulatable) use of the material. Demand elasticity for propane in this use is relatively low (because of the costs of converting to an alternate energy source), and bottling is done by small local companies. Supply elasticity for propane is low. The price of natural gas will not be greatly influenced by changes in demand from this quarter.

Sulfuric Acid as a Waste Product - sulfur emissions are often produced as a waste product of industrial production processes. Sulfuric acid from waste gasses is often (in fact, because of clean air regulations, most often) collected and disposed of. Demand elasticity for sulfuric acid is low; there are often no economic substitutes for the substance. Supply elasticity, however, is high because the raw input - waste gas - is not useful in any other application.

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APPENDIX B INNOVATION IN THE CHEMICAL INDUSTRY

To understand how TSCA might affect chemical innovation, it is necessary to have some understanding of the history and future trends of both the nature and origins of new chemicals. Among the significant factors to be considered are the relative importance of small and large firms, and of new entrants and established companies,; the contributions of academic research; the importance of government and of private funding for new chemical development; the relative emphasis on product and process research and development; and the differences among the various industry sectors for each of these factors at various times. It is also necessary to understand what changes may be occurring in the structure and in the environment of the U.S. chemical industry in order that such changes are not mistakenly attributed to environmental, health, and safety regulations in general, or to TSCA in particular.

This appendix begins with a model of the innovation process in industry which is presented to provide a context for the subsequent discussion. This model takes a long-term view of the innovation process; it is not concerned with how a particular firm manages its innovative activities at a particular point in time, but rather with how the pattern of innovation changes as a firm, a productive unit, or an industry sector evolves over time.

Next, data are presented on the basic structure of the chemical industry that help to understand the response to regulation and the nature of innovation in various sectors. Subsequent sections describe trends in the allocation of resources to innovation in the industry, and review what is known from the literature about the nature and sources of new chemical products. Following an assessment of future trends in competitive and other pressures on the industry, the appendix closes with a summary of findings.

B.1 A Model of Technological Innovation*

The process of technological innovation involves the creation, design, production, first use, and diffusion of a new technological product, process or system. While the process of technological innovation is sometimes viewed as synonymous with R&D, in fact, organized R&D is only one of several kinds of innovative activity -- in some cases R&D comes only after the fact of an innovation, or not at all. The process of technological innovation can happen rapidly, or it may require an extended period of time. The changes that occur in the costs, the performance, or the characteristics of a technology may be major or incremental, but the total of the incremental changes over a period of time can be as important as the dramatic breakthroughs in improving the quality or reducing the cost of a product.

Technological innovation involves matching, in a new way, a social or economic need with capabilities drawn from science, technology, or craft. Innovative activity can be a risky business. It is not possible to know in advance whether any particular project will be successful. The greater the advance sought, the more uncertain the outcome.

Four indirect approaches are used to measure technolgocial innovation. The first, measures inputs to the process of technological innovation, such as the R&D budget or the number of scientists working in an area. The second, measures intermediate outputs, such as the number of patents awarded, the number of technical papers published, or the number of new chemical entities synthesized. The third, measures the performance of a product or process, such as its weather resistance, dispersability, durability, or cost. The fourth, measures the amounts of various inputs required to produce a product, such as hours of labor, barrels of oil, or dollars worth of capital equipment. None of these measures is entirely satisfactory, but all are used in various studies discussed below.

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*This section is drawn from (Hill, 1979) and (Hill and Utterback, 1979).

In the market-oriented U.S. economy, technological innovation nearly always occurs in private firms, although government plays many roles in supplying the resources necessary for innovation and for creating the environment within which it must happen. However, with rare exceptions, government itself does not innovate. Instead, it must find ways to influence the rate and direction of technological innovation in private firms. Similarly, only rarely do other institutions in our society, such as universities or special interest organizations, engage in technological innovation. When they do, it is nearly always by cooperating with or establishing a profit-making venture to commericalize an idea or an invention.

Firms choose among the available products, strategies, and technologies in order to maximize some measure of profitability. A major concern of a firm is to increase the probable rewards to success and to reduce the risk of failure in the marketplace. Therefore, firms must consider the profits likely to result from an innovation and the technological risk involved, when deciding to attempt it.

However, they must also consider another and more important risk -- the risk that in failing to innovate, an existing line of business may be taken over by a competitor who does. Thus, an important incentive for firms to attempt risky technological innovation is their desire to survive in the face of effective competition or rivalry from other firms. Such rivalry can be especially effective if the competitor is a new entrant who has a new technological product or process that is superior to those of the existing firms in the industry.

At the level of the firm, several factors tend to increase the extent and success of innovative activity: a flexible organizational structure; a high diversity of staff experience; an adequate financial condition; a good recognition and understanding of market needs; a good recognition and understanding of competitive and other environmental pressures; a willingness, ability, and need to take risks; and a set of technological possibilities. Innovation is facilitated if a firm is experiencing, or can anticipate, a rapid growth in demand for its products, and if the workers, owners, and managers can expect to earn a financial reward for their efforts. Government policies such as fiscal and monetary policy, regulation policy, labor policy, and industry structure policy can act to increase or decrease the rate of technological innovation in a variety of ways.

The continuing entry of new firms is an important determinant of the degree of rivalry in an industry, because new entrants, in hopes of becoming a major factor in an industry, have a greater incentive to take risks. In the absence of such new entrants, there is a tendency for the degree of risk taking in existing firms to decline. In existing firms, the thinking habits of entrepeneurs and their patterns of search are likely to be highly constrained by the forms of the technology and the organization they already have. Therefore, they are likely to search for new technologies more narrowly than do new entrants.

Small new ventures and larger firms entering a business for the first time, introduce a disproportionate share of the innovations that create major competitive threats and rivalry. Established firms often respond to a new entrant's invasion of their product line with redoubled creative effort and investment in what they already know well. Even though it may be crude, the new technology may have greater performance advantages in certain submarkets, and gain ground by competing there first. Use of the new technology then expands as it captures a series of submarkets. The new technology often has a much greater potential for improvement and cost reduction than does the existing technology. Thus, price cutting by established units as a defense may be ineffective.

Firms must become more specialized and efficient to exploit innovations over an extended time. This drives them toward a more stable production process and a more structured organization. Most established large firms have evolved from small, disorganized, and highly innovative beginnings. Demands for greater sophistication, uniformity, and lower cost in the product create an ongoing demand for the development and the improvement of both product and process. This means that product design and process design become more and more closely interdependent as a line of business develops. A shift from radical to evolutionary product innovation usually occurs as a result of this interdependence, and is accompanied by heightened price competition, and by an increased emphasis on process innovation. Small-scale units that are flexible and highly reliant on manual labor, and that use general-purpose equipment, develop into units that rely on automated, capital-intensive, high-volume processes. Thus, innovative patterns, production processes, and the level of production capacity all change together in a consistent, predictable way over time.

B.2 The Structure of the Chemical Industry

The chemical industry includes many sizes and types of firms producing many product types and using many different technologies. It is one of the most vital sectors of the U.S. economy, whose sales growth and profits have been larger than the average in manufacturing. (Keegan, 1977; Landau, 1979) The total output of the industry is expected to increase at a rate of 4-6% in real terms through 1985. (A.D.Little, 1978; Keegan, 1977; Boyden 1976) This rate is lower than in the past but is still strong when compared with the U.S. industrial average. (C&E News, 1979a; A.D.Little, 1978; Keegan, 1977)

The U.S. chemical industry has a net positive trade balance, presently contributing a balance greater than $5 billion per year. (C&E News, 1979a) This is expected to continue even in light of the anticipated competition from the oil producing nations that are now constructing their own petrochemical plants. The predicted strength of the U.S. industry has been attributed, among other things, to its heavy use of natural gas as a primary chemical feedstock. Owing in part to the history of price regulation, natural gas prices have not risen as rapidly as that of oil, especially oil in other importing countries. The chemical industries of most other nations rely more on oil and have experienced greater price increases for their primary feedstock. It is, therefore, likely that the industry in the U.S. will be able to maintain competitive prices in the increasingly competitive world market. (Business Week, 1980; C&E News, 1979b)

The chemical industry produces three fundamental product types: basic chemicals, intermediates, and finished products. Basic chemicals form the bulk of the industry output. This sector is dominated by large producers, and is becoming more and more controlled by chemical subsidiaries of the large petroleum firms. After an aborted attempt in the early sixties to enter the chemical industry, their immediate access to feedstock and to capital has allowed the petroleum firms to stake out the basic chemical sector as their province over the last ten years.

Growth in intermediates is expected to exceed the overall real growth rate of 4-6% anticipated for the years 1977-1985. Intermediates include many specialty products that have high profit margins and comparatively rapid turnover in the market. This sector contributes the greatest proportion of new chemical products. (Foster D. Snell, Inc., 1975)

The finished product sector is the most diverse of the three sectors. Finished products use basics and intermediates as inputs. New discoveries occur in this sector although with a lower frequency than for intermediates. The need for improved intermediates often originates in finished product firms. The identification of a market need that can be filled by a finished product or the requirement for improved finished product performance often stimulates the development of new chemical intermediates. Finished products also have large public exposure, and safe chemicals are becoming a very high priority for this sector due to changing public expectations regarding chemical safety, and the growing market for safety and government regulation of chemicals. (Business Week, 1979)

The chemical industry includes approximately 7,000 firms operating in 10,000 establishments. Forty-seven percent of the firms are manufacturers rather than processors or mixers; the manufacturers are the firms that are presently primarily concerned with TSCA. The extent to which processors and mixers will have to be concerned with TSCA is not yet settled.

The Standard Industrial Classification (SIC) system recognizes 28 four-digit classes within the chemical industry (SIC 28) as shown in table B.1. Nearly all of these sectors will be directly affected by TSCA. In addition, the products of or the inputs to the following two-digit sectors are also likely to be affected by TSCA:

20	Food and kindred products
26	Paper and allied products
29	Petroleum refining and related industries
30	Rubber and miscellaneous plastic products
31	Leather and leather products
32	Stone, clay, glass, and concrete products
33	Primary metals industries

This analysis is primarily concerned with SIC 28 and the chemical activities of firms in SIC 29. Resource and data limitations preclude examination of the other sectors. As with all analyses based on the SIC system, there are problems of overlapping markets, firms that span several sectors, and inappropriate aggregation of the data.

Concentration in the chemical industry as a whole is moderate measured in terms of the value of shipments. The Kline Guide estimates the four-firm concentration ratio at 35% and the ten-firm ratio at 50%. (Keegan, 1977) It argues that in comparison with other capital intensive industries such as automobiles, tires, or aircraft this concentration ratio is low. The real concern, however, is concentration ratios within

TABLE B.1

Standard Industrial Classification System for the Chemical Industry

2812	Alkalies and chlorine
2813	Industrial gases
2816	Inorganic Pigments
2819	Industrial inorganic chemical nec*
2821	Plastics materials and synthetic resins
2822	Synthetic Rubber
2823	Cellulosic manmade fibers
2824	Organic fibers, non cellulosic
2831	Biological Products**
2833	Medicinals and botanicals**
2834	Pharmaceutical preparations**
2841	Soap and other detergents
2842	Polishes and sanitation goods
2843	Surface active agents
2844	Toilet preparations
2851	Paints and allied products
2861	Gum and wood chemicals
2865	Cyclic crudes and intermediates
2869	Industrial organic chemicals nec*
2873	Nitrogenous Fertilizers
2874	Phosphatic Fertilizers
2875	Fertilizer mixing only
2879	Agricultural chemicals nec*
2891	Adhesives and sealants
2892	Explosives
2893	Printing Ink
2895	Carbon Black
2899	Chemical preparation nec*

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* nec - not elsewhere classified

**Exempt from the TSCAct

the industry subsectors shown in Table B.2 for four-digit groups. As shown in the table, the most concentrated sectors are:.

2812	Alkalies and chlorine
2813	Industrial gases
2822	Synthetic rubber
2823	Cellulosic man-made fiber
2824	Non-cellulosic organic fiber
2841	Soaps and detergents
2861	Gum and wood chemicals
2892	Explosives
2895	Carbon black

This assessment agrees with those by Arthur D. Little (1978) and the Kline Guide (Keegan, 1977) regarding the most concentrated sectors. The least concentrated sectors are:

2851	Paints and allied products
2875	Fertilizers-mixing only
2891	Adhesives and sealants
2899	Chemical preparations (not elsewhere classified)

Table B.3 presents four-firm concentration ratios based on number of establishments, on value added, and on total employment. (U.S. Bureau of Census, 1972) These data confirm the findings regarding the most and least concentrated sectors, reached from the concentration ratios based on the value of shipments.

Concentration ratios provide some insight into the ability of different sectors to cope with the costs of regulation. Firms in the less concentrated sectors face a more competitive situation than ones in the more concentrated sectors, and may not be able to pass on the costs of compliance. In addition, sales of firms in the less concentrated sectors may be more affected by unregulated substitutes than the larger firms. Furthermore, the generally larger firms in the more concentrated sectors are more likely to be able to influence the nature of the regulations governing their behavior.

A brief review of the adhesives and sealants sector illustrates through small firms the types of problems that may be encountered in the

TABLE B.2

Chemical Industry Concentration Ratios Based on the Value of Industry Shipments in 1972

		4 firm	8 firm	20 firm	50 firm
2812	Alkalies and Chlorine	72	91	99+	100
2813	Industrial Gasses	65	81	93	98
2816	Inorganic Pigments	52	72	91	99
2819	Industrial inorganic chemical nec	34	52	76	93
2821	Plastics materials and resins	27	41	65	90
2822	Synthetic rubber	62	81	98	100
2823	Cellulosic man-made fibers	96	X	100	X
2824	Organic fibers non-cellulosic	74	91	99+	100
2841	Soal and other detergents	62	74	85	92
2842	Polishes and sanitation goods	43	54	65	78
2843	Surface active agents	8	42	64	89
2844	Toilet preparations	38	53	74	91
2851	Paints and allied products	22	34	51	66
2861	Gum and Wood chemicals	68	83	94	99
2865	Cyclic crudes and intermediates	34	52	77	96
2869	Industrial inorganic chemicals nec	43	57	74	92
2873	Nitrogenous fertilizers	35	53	84	100
2874	Phosphatic fertilizers	29	47	83	99
2875	Fertilizers mixing only	24	38	57	74
2879	Agricultural chemicals nec	39	57	76	89
2891	Adhesives and sealants	19	31	52	76
2892	Explosives	67	86	98	99+
2893	Printing Ink	39	54	75	88
2895	Carbon Black	74	99+	100	--
2899	Chemical preps nec	16	26	41	58

Source: U.S. Bureau of the Census

less concentrated sectors. Adhesives and sealants is one of the least concentrated sectors of the chemical industry. The largest firms in the industry are H.B. Fuller, National Starch, 3 M, and U.S.M. Sales and concentration data for adhesives and sealants do not reflect captive markets. Georgia-Pacific dominates the plywood and wood products industry and develops and manufactures all the adhesives it uses internally. Georgia-Pacific's internal use of adhesives is equivalent to a major fraction of all U.S. adhesive sales, and if included as a manufacturer, it would top the list of major producers.

This sector is characterized by a high acquisition rate, which reflects, in part, the high margins available in specialty adhesives, and the growing penetration of adhesives into the fasteners market. These acquisitions, which are dominated by large firms, both increase their market share and also help them acquire new products. Large firms not only acquire small ones, they also acquire divisions of other large firms. Furthermore, start-up and entry of new firms has come to a halt. An indication of the high acquisition rate is the increasing concentration of this sector over time. (Frost and Sullivan, 1976)

According to Frost and Sullivan (1976) the problems faced by the small firms in the adhesive and sealants sector, which may be similar to the problems of the other less-concentrated sectors, are:

- a substantial proportion of large firms are involved in acquisitions
- captive markets that cannot be penetrated
- increasing capital outlays due to rising costs in an increasingly aggressive environment.
- an inability to acquire capital

Based on the concentration data, the sectors composed of small firms that may have trouble dealing with regulatory costs are:

TABLE B.3

Measures of Chemical Sector Concentration

SIC Code	Sector	Number of Firms	Number of Establishments	Percent of Establishments Owned by Top 4 Firms	Percent Value Added by Top 4 Firms	Percent Total Employment by Top 4 Firms
2812	Alkalies and chlorine	28	48	38	71	79
2813	Industrial gases	105	503	59	67	52
2816	Inorganic pigments	77	114	17	54	50
2819	Industrial inorganic chemicals nec*	166	384	8	39	38
2821	Plastics materials and resins	193	323	7	30	29
2822	Synthetic rubber	50	59	15	65	59
2823	Cellulosic man-made fibers	12	18	50	X	X
2824	Organic fibers, non-cellulosic	36	61	31	78	69
2841	Soap and other detergents	577	642	4	65	46
2842	Polishes and sanitation goods	1022	1108	2	46	19
2843	Surface active agents	151	178	6	29	23
2844	Toilet preparations	593	645	2	41	18
2851	Paints and allied products	1318	1599	3	23	19
2861	Gum and wood chemicals	118	139	9	70	62
2865	Cylic crudes and intermediates	124	174	12	49	30
2869	Industrial organic chemicals nec*	351	513	8	49	37
2873	Nitrogenous fertilizers	47	73	16	39	33
2874	Phosphatic fertilizers	66	145	17	29	25
2875	Fertilizer mixing only	422	627	7	29	8
2879	Agricultural chemicals nec*	297	388	3	47	29
2891	Adhesives and sealants	317	463	12	20	13
2892	Explosives	55	92	39	69	67
2893	Printing ink	213	407	22	35	39
2895	Carbon black	11	37	62	74	69
2899	Chemical preparations nec*	1485	1606	1	16	9

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* Not elsewhere classified

Source: U.S. Bureau of Census (1972)

SIC	
2581	Chemical preparations, n.e.c.
2899	Paints and allied products
2875	Fertilizers - mixing only
2891	Adhesives and sealants

Small firms can also be expected to have difficulty meeting regulatory costs in the sectors that are dominated by large firms in which there is also a significant portion of small firms in a very competitive environment. These include:

SIC	
2841	Soap and other detergents
2842	Polishes and sanitation goods
2844	Toilet preparations
2879	Agricultural chemicals n.e.c.

B.3 Inputs to the Innovation Process in the Chemical Industry

Three critical inputs to the process of innovation are R&D expenditures, R&D personnel, and corporate R&D strategies. There have been major changes over time in both R&D strategies and R&D expenditures. R&D personnel numbers have not changed significantly in recent years; however, it is claimed that the productivity of research personnel has . (Landau, 1979) The following sections outline the changes in each of these areas.

B.3.1 Research and Development Expenditures*

Industry spent about $1 billion annually on chemical R&D from 1969 through the early seventies. In 1978 expenditures surpassed $2.2

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*The information in this section is largely drawn from "Facts and Figures for Chemical R&D" in the July 23, 1979 issue of Chemical and Engineering News.

billion, excluding those for pharmaceutical research. Government funds only a small percentage of chemical research, contributing an additional 13% to this total. It should be noted that these figures represent expenditures for chemical R&D in SIC 28 only and that they also include non-chemicals R&D expenditures by SIC 28 firms.

Chemical industry R&D spending, not adjusted for inflation, increased at an average annual rate of 9% throughout the seventies. In real terms, however, spending for 1967 through 1972 fell approximately 25%; in recent years, R&D investment in real terms has been increasing at 2-3% per year. (C&E News 1979a) Since the 1979 inflation rate was greater than 13%, R&D spending for this year may not show any real gain. The small real gains of recent years may be even smaller in view of the fact that they are estimated using the average rate of inflation, and that costs of salaries and other contributions to R&D in chemicals have been rising faster than average costs in the economy. (Keegan, 1977)

As shown in Table B.4, R&D expenditures averaged 3 - 3.8% of chemical industry net sales during the seventies. This is about one percentage point below the investment of 15 years ago, but is still higher than the U.S. industrial average. This declining trend in chemical R&D reflects the overall U.S. industrial pattern: U.S. industry R&D as a portion of the GNP has fallen since 1964, and now averages about 2.2%, down from just under 3% at its high point. (Business Week, 1979)

The NSF (1977) survey of R&D expenditures divides chemical research into basic, applied, and development. Industry funds have grown most rapidly in recent years for applied research, more slowly for development, and have fallen behind the inflation rate for basic research. The proportions in 1978 were 11% for basic research, 41% for applied research, and 48% for development (not including spending on drugs). In basic research, the major portion of funding goes to the physical sciences as opposed to engineering by a ratio of almost two to one. Applied research funds are devoted predominantly to industrial chemicals and synthetics. The breakdown on spending for development was not available.

Table B.4

Chemical Industry R&D Expenditures

Year	R&D as % Net Sales
1958	3.8
1963	4.3
1964	4.5
1965	4.3
1966	4.4
1967	4.6
1968	4.2
1969	4.2
1970	3.9
1971	3.8
1972	3.6
1973	3.5
1974	3.2

Source: National Science Foundation (1977)

Chemical research activities can also be categorized into defensive, environmental, product, and process areas. An authoritative breakdown on R&D spending for these areas is not available. However, it is known that R&D for new product development has decreased, and that product and process improvements are becoming the major goal of the industry. (See section B.3.3.)

The Snell survey of the chemical industry examined 1972 R&D expenditures. (Foster D. Snell, Inc., 1975) Their survey excluded product maintenance costs and commercial development expenditures. The remaining R&D expenditures were divided among new products, 44%; new applications, 36%; and other, 20% Another source reported the allocation of R&D expenditures for 1974 as 31% for new products and 51% for new applications. (Chemical Week, 1975) The differences among these two sources reflect different time periods, different measurement conventions, and different sectors of the industry.

Landau (1979) estimates that recent chemical R&D funds are divided as follows:

Topic Area	Expenditure Allocation (%)	
	1978	1979
improving existing products	58	62
new processes	16	20
new products	26	18
pollution control	5	4
energy related	4	3

These data show a 30% drop in new product investment by the industry from 1978 to 1979. Combined with the Snell survey and Chemical Week data, they indicate that a major decrease is occurring in new product investment by the chemical industry.

[illegible] is possible to conclude from statements by the industry reported in the trade press and from the importance of new products to small innovative firms, that large firms, more than small, have been cutting back on new product development efforts. According to Landau's data, these funds are being shifted toward product and process improvements rather than being directed to meet environmental or regulatory demands.

The large diversified chemical firms dominate the statistics on industrial R&D spending. More than 70% of R&D spending for the chemical and allied products industries is spent by the top 20 firms; for industrial chemicals the fraction is greater than 90%. (C&E News, 1979a)

Mansfield (1968) has demonstrated that historically R&D funding in chemicals has increased more than proportionately with firm size. The chemical industry is the only major industry in which this trend is maintained through to the largest firms. In all other industries, mid-size firms are proportionately more heavily engaged in R&D spending.

In a more recent analysis, Soete (1979) found an increasing relative R&D expenditure with firm size in chemicals. However, he did not consider firms with sales of less than $100 million per year, effectively omitting small firms from the analysis. Soete linked R&D expenditures with inventive activity. However, Chemical and Engineering News (1979a) has pointed out that measures of innovation based on R&D funding:

> ...provide little insight on the quality of R&D or on the ill-defined ties between R&D efforts and innovation and economic development. It is increasingly evident that scientific and technological problems are not necessarily solved simply by throwing more money at them; more research is not necessarily better research.

The model of technological innovation outlined in section B.1 shows that as firms enter a more mature phase, R&D becomes directed toward improvements in products and processes and away from risky new ventures. As firms grow more successful they become locked into particular products. Investments in R&D increase not for new product developments but for improvements in existing facilities and product lines.

B.3.2 R&D Personnel

Employment of R&D scientists and engineers in the chemical and petroleum industries is shown in table B.5. Scientists and engineers in these data are defined as individuals having had at least the equivalent of a four-year college program in science or engineering The reported equivalent numbers are adjusted to reflect time devoted only to R&D.

The data show an increase in chemical R&D employment in the late fifties, reaching approximately 30,000 (excluding pharmaceuticals and petroleum) in 1960. From 1960 to 1976 employment ranged from 29,200 to 32,400. It was somewhat higher in 1976, following a period of decreased employment during the early seventies.

Research employment is at best a rough measure of investment in research efforts. Furthermore, the productivity and efficiency of research have increased dramatically since the late fifties due, for example, to improved instrumentation and to the use of computers. Researchers today are able to accomplish substantially more than their

TABLE B.5 Number of Full Time Equivalent R&D Scientists and Engineers 1957 to 1976

Industry	SIC CODE	Thousands of Employees In January of Each Year									
		1957	1958	1959	1960	1961	1962	1963	1964	1965	1966
Total.	. . . .	229.4	243.8	268.4	292.0	312.1	312.0	327.3	340.2	343.6	353.2
Chemicals and allied products	28	29.4	31.0	33.5	36.1	37.0	36.5	38.3	37.8	40.0	40.0
Industrial chemicals	281-82	18.0	18.8	20.2	21.8	22.9	21.6	22.9	23.6	25.7	24.7
Drugs and medicines	283	4.7	5.1	5.9	6.0	6.2	6.8	6.9	7.3	7.7	8.0
Other chemicals	284-89	6.7	7.1	7.4	8.3	7.9	8.1	8.5	6.9	6.6	7.4
Petroleum refining and extraction	29,13	6.9	7.4	7.7	9.2	9.0	9.1	8.9	9.0	9.7	10.2

Industry	SIC CODE	Thousands of Employees In January of Each Year									
		1967	1968	1969	1970	1971	1972	1973	1974	1975	1976
Total.	. . . .	367.2	376.7	387.1	384.1	359.3	349.9	356.6	358.2	360.8	361.6
Chemicals and allied products	28	38.7	40.8	42.2	42.1	42.5	40.9	40.7	41.6	44.9	46.4
Industrial chemicals	281-82	22.7	23.2	23.6	22.9	22.6	19.7	19.8	19.8	22.1	22.4
Drugs and medicines	283	9.3	10.0	10.0	11.6	12.3	11.8	11.2	12.0	13.1	14.1
Other chemicals	284-89	6.7	7.5	8.3	7.6	7.6	9.5	9.7	9.8	9.8	10.0
Petroleum refining and extraction	29,13	10.4	11.2	11.9	11.5	10.8	8.3	8.2	8.2	8.4	8.9

Source: NSF (1977)

counterparts of the fifties and sixties. (Landau, 1979) Finally, R&D is only one component of the innovation process. Thus, there is no way to know how the level of R&D employment affects the overall rate of technological innovation.

B.3.3 R&D Strategies

Industrial chemistry began in the mid-nineteenth century with the creation of the synthetic dye industry. The major growth in chemicals for the first 40 to 50 years occurred in Germany and the United Kingdom. By the turn of the century, the U.S. industry had begun an expansion and maturing that has continued to the present.

Davies (1978) has depicted three eras of industrial chemistry. The first period he characterized as "science-push." In this period basic discoveries led to the introduction of products, universities worked closely with industry, and growth occurred rapidly. The second period was characterized as "market pull." Market pull reflects the situation where market needs are identified and teamed closely with the goals of research. Research is actively pursued, pay-offs are high, and research labs become institutionalized in firms. As this period evolved, the market became a tougher place in which to survive and current and competitive pressures grew. This led to the third era - "resource supply and husbandry." In this period efficient use of feedstocks has become essential, and management control of R&D is more stringent and skeptical. Research efforts have turned inward in this period in efforts to improve efficiency. Product and process improvements rather than product discovery are high priority research efforts.

The chemical industry today is in its third period. The evidence for this can be seen in trade journals and reports on research. Dupont among other companies has introduced changes in its corporate planning and research investments. (Pappas, 1978; Gubitosi, 1979; Burke, 1979) Changes in the management of R&D are evident in many companies. R&D management was originally an easy task, there was little pressure to prove the value of research. Today management of R&D is more rigid and project selection is measured against successful products with strong market positions. (Landau and Brown, 1978; Landau, 1979; Maisel, 1980)

The trade literature reports a major reevaluation of R&D efforts among the larger companies in the industry. (Gubitosi, 1979; Verespecj, 1979) Efficiency and productivity are critical to corporate survival, and this efficiency will be achieved through improvements in production processes. (Verespecj, 1979, Kline, 1978) Old products have top priority in chemical firms, and innovation is geared toward improving their characteristics and production. (Chemical Week, 1977) Projects that promise short pay-off horizons and low risk are being preferred to high risk investments. (Landau and Brown, 1978)

B.4 Evidence on Trends in Chemical Innovation

The Foster D. Snell study (1975) estimated that up to 1000 new chemicals are marketed each year. Seven hundred of these are intended for R&D purposes, leaving about 300 new chemicals of potential interest for TSCA purposes. In the following, discussion the classes of chemicals into which these new products fall are described.

To date, a comprehensive study or collection of data to provide a clear picture of chemical innovation has not been made. An attempt has been made here to determine active areas of growth in chemicals and some of the characteristics of that growth, by examining three perspectives: previous studies of chemical innovation, the first round of Premanufacturing Notice Data, and chemical patent activity. All of these sources have limitations.

B.4.1 Previous Studies of Chemical Innovation

A number of studies of particular aspects of chemical innovation are summarized in Table B.6. Most are older case studies that lack the recent data necessary to understand the characteristics of chemical

TABLE B.6 A Summary of Studies of Chemical Innovation

Study	Types of Study	Time Period	Measure of Innovative Activiy	Source of and Critical Inputs to Innovation	Role of Small and Large Firms
Arthur D. Little Impact of TSCA Proposed Premanufacturing Notification Requirements (1978)	1. Interview 2. Output analysis 3. Patent examination	1973-1978	1. Patent activity 2. Phone survey 3. 25 "new" chemicals selected from Chemical Week Buyer's Guide	Innovation is occurring in all sectors of the industry It's growing fastest in organics (intermediates & cyclic crudes)	Not addressed but assumed small firms had a major role
Boyden, J. W. A Study of the Innovative Process In the Plastic Additives Industry (1976)	Case study of 3 types of plastic additives	Post WW II until the present	Selected product outputs and their achieved market sales	In commercializing firm as opposed to the users of the additives. Development was in response to a perceived need or new potential	The role of each was not specifically addressed but it was apparent from the study that larger firms were believed to be more able to innovate
Enos, J. L. Petroleum Progress and Profits (1962)	Case study of the petroleum cracking process	1900-1960	Process discoveries in the petroleum industry	1. Medium and small firm R&D labs 2. Some independent inventors 3. Strong individual played a vital role in every breakthrough	Small and medium firms were the risk-takers in the industry
Foster D. Snell Study of the Potential Economic Impacts of the Proposed TSCAct as Illustrated by S. 776 (1975)	Survey and interviews	1970-1974	Product introductions by selected firms within particular sectors of the industry measured against per dollar sales	Source of innovation is in all sectors with a greater percentage arising from small firms, small firms were defined as those with less than 30×10^6 dollars in sales	Small firms in organics had up to 100 times the activity of larger firms, in inorganics small firm activity was 5 to 10 times greater

Table B.6 continued

Study	Types of Study	Time Period	Measure of Innovative Activity	Source of and Critical Inputs to Innovation	Role of Small and Large Firms
Freeman, C.A. "The Plastics Industry: A Comparative Study of Research and Innovation" (1963)	Case study of the plastics industry	1920-1960	Research expenditures patent activity, and significant innovations	Large firms dominated R&D, plastic products and patents. German & American dominance the industry sector Basic research in universities was a critical input but industry was greatest input.	Not specifically addressed but the large firms dominated innovation of major products in this sector
Gibbons, Michael "Factors Affecting Technological Innovation in British Industry" (1973)	Case studies in chemical, electrical and mechanical industries		Products and process innovations themselves	Discovery push and market pull both operate as stimuli. Four types of innovations: science discoveries, technological discovery, customer need, management by objectives. The market and management control are best stimulators of innovation	Not addressed
Greenberg, E., C.T. Hill and D.J. Newburger, Regulation, Market Prices, and Process Innovation: The Case of the Ammonia Industry (1979)	Case study and economic modeling	1917-1972	Productivity of each input factor, as well as qualitative assessments of new capabilities	Innovation from original producing firms, government laboratories, and engineering design and construction firms	Small firms own and operate ammonia facilities, but play only a small role in innovation. Currently, most innovation from engineering design firms
Jewkes, J., D. Sawers and R. Stillerman The Sources of Invention (1969)	Case histories of major industrial innovations	1885-1969	The actual innovations themselves		Not addressed

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TABLE B.6

Study	Types of Study	Time Period	Measure of Innovative Activity	Source of and Critical Inputs to Innovation	Role of Small and Large Firms
Langrish, J., M. Gibbons W.G. Evans and F. R. Jevons Wealth from Knowledge (1972)	Case studies of United Kingdom Queen's award winners for innovation	1966-1967	The products themselves and their value measured as a Queen's award winner	There are multiple sources of innovation, but the entrepreneurial individual in whatever setting is critical. There is no major link between basic discoveries and technological innovation	Not addressed
Leibhafsky, H.A. Silicones Under the Monogram (1978)	Case study of the development of silicone at G.E. and an overview of other industrial research efforts	1900-1974	Actual products and process improvements	The source of innovation is the innovative industrial research lab which combines independent discoveries into major innovations	Small firms operate to either promote or synthesize discoveries of independent inventors
Mueller, W.F. "The Origins of the Basic Inventions Underlying DuPont's Major Product and Process, 1920-1950" (1962)	Case study of 18 product, and 7 process innovation at DuPont	1920-1950	The actual product and process improvements and the value to the company	13 out of 18 product improvements came from outside DuPont. 5 out of 7 process improvements ments originated at DuPont	Large firms are better at improving and building on product innovations. They are not the most efficient at generating new products but certainly are most efficient at improving and producing them.
Robertson, A.B. Success and Failure in Industrial Innovation: Report on Project SAPPHO	A paired comparison of 43 successful and unsuccessful chemical and scientific instrument innovations		Selected successful innovations paired with project failures	Successful innovations used more outside technology and advice, more frequently contacted customers. More planning and careful preparation was used in successful innovations. Marketing was critical and an understanding of user need separated successful from uncursful innovation	Not specifically addressed

product innovation as it now occurs. Several of the studies used surveys and interviews to derive a picture of innovation. The 1975 Foster D. Snell study is the most recent comprehensive survey of innovation in chemicals.

Both the Snell study and the ADL study also identified subject areas of highest chemical innovation activity. The most active areas of chemical development reported by the ADL study were chemical catalytic preparations, soaps and detergents, surface active agents, flavors and perfumes, and synthetic organic chemicals. These trends were determined by conversations with industry representatives, a review of 25 "new" chemicals, and an analysis of patent trends. The Snell survey found that the soaps, plastics, and industrial organics sectors dominate in new chemical development. Snell based their analysis on survey respondents who provided a breakdown of product investment by class.

These studies were examined to determine the role of the small firm in chemical innovation. Totally consistent results cannot be obtained from these studies, since their definitions of small firms differed and since several studies described the invention process rather than the innovation process.

Large firms dominate the production of basic chemicals and play major roles in finished products. They also control the largest number of research personnel, and devote proportionately the largest amount of funds to R&D. (Mansfield, 1968; Mansfield, 1972; Soete, 1979) It is not clear, however whether large firms are responsible for the greater portion of significant product innovations in the industry. This is especially true if significant product innovations are thought of as those that open up entirely new lines of business.

The largest firms in the chemical industry are typically diversified into many product lines and businesses (C&E News, 1979a). This has produced corporations that make R&D decisions based on expected profitabiliy and assured pay-off. (Landau, 1979) In many cases, these firms prefer to make existing products and to use production plants that are fully depreciated and far down the learning curve, rather than to risk making new products that require expensive plants and equipment. New products and new process technologies that do not have a high probability of achieving a profitable position in the market are generally avoided. (Landau, 1979)

Small firms in the industry play three roles. First as non-innovative, marginal producers; second, as non-innovative producers of specialty chemicals, and third, as innovative producers of high quality specialty products and intermediates. The third role of the small firm is of greatest concern in this analysis.

A study of innovation at DuPont by Mueller (1962) showed that 13 out of 18 product innovations originated outside the firm, and that the real successes of DuPont's research efforts were in making process and product improvements. DuPont was found to be better at tailoring a product to market demands and at efficiently producing that product than it was at discovering new products.

Mansfield (1968, 1972) also found that large firms often develop products that originally came from sources outside the firm. He concluded that R&D in large firms is proportionately more productive than in small ones. For firms with sales greater than $100 million per year, Soete (1979) found that the largest chemical firms devote a greater percentage of their sales to R&D than do the somewhat smaller firms. However, both Mansfield and Soete limited their studies to what would be considered large firms for the purpose of the present analysis.

The Snell survey of the industry most closely approximates a comprehensive analysis of innovation. It surveyed companies that accounted for 24% of the total sales of the industry in all major segments of the industry except pharmaceuticals. The respondents were divided as follows:

Sales Range ($/year)	Number of Respondents
greater than 1,000 million	4
between 100 million and 1,000 million	27
less than 100 million	14

The role of the small firm was addressed with a sample of 9 firms, each with less than $30 million in sales in 1972. The Snell study found that for inorganic chemicals "new product activity appears to be five to ten times as great among the small companies." In industrial organics, for which new product innovation is predominately "custom chemical" work, they found that activity is one hundred times as great in the small firms. They stated, however, that because of the small number of firms sampled, these findings are not statistically significant. The studies of innovation examined in the current trade and professional press make this doubtful. Small firms play an important, but not fully understood or quantified, role in chemical innovation. Furthermore, small, innovative chemical firms have the following characteristics:

- they are more dependent on new products than large firms, (new products are a larger proportion of sales in small firms),
- they obtain their new product ideas when their customers describe special characteristic that they require,
- they have larger chemical firms as important customers who use the small firms' products as production intermediates or additives,
- they concentrate on specialties, often for a single buyer on a short term contract basis,
- they depend in a large measure on their ability to respond quickly to an order to obtain a contract,
- they do not have the staff to carry out toxicology testing and other compliance requirements,
- they rely on trade-secrets to protect their products,
- they can usually pass on increased material costs to their customers but may have trouble passing on increased regulatory compliance costs if such costs fall unevenly on different products and firms,

- they may rely on their customers to handle the requirements of TSCA,
- they do not have the resources to appeal an EPA ruling,
- they fear take-over or loss of their markets if the different treatment of old and new chemicals under TSCA creates an incentive to they use of established chemicals in preference to new, potentially safer ones.

B.4.2 Premanufacturing Notice Data

Premanufacturing notices (PMN's) may become a means for measuring chemical innovation. Currently, there are too few PMN's to provide statistically significant data, and, of course, there are no PMN's before late 1979. The following information is derived from the first 57 PMN's submitted to EPA. Information is not complete for all 57 because of unreported data, claims of confidentiality, or inaccessible data. Totals in some categories exceed 57 since some PMN's report data in more than one category.

Type of Company Submitting	
large (greater than $100 million in sales per year)	26
medium ($50 million to 100 million)	7
small (less than $50 million)	5
subsidiary of larger firm	11

Primary Product of Submitting Firm	
plastics	13
coatings and resins	16
flame retardants	1
detergents	1
adhesives	1
photographic supplies	1

Initial Production Volume	
not reported or claimed confidential	13
less than 500 lbs.	4
20,000 to 40,000 lbs.	1
15,000 to 100,000 lbs.	2
200,000 to 300,000 lbs.	3
500,000 to 1,000,000 lbs.	1
2,000,000 lbs.	2

Type of Toxicity Data Submitted	
acute animal studies	24
subacute animal studies	1
eye and skin irritation tests	23
bacterial mutagenicity	12
chronic	0
no data	27

These PMN data may be useful in assessing chemical innovation, but the data presently being provided to the public is not entirely adequate for that purpose. (Chemical Week, 1980; Jellinek, 1980)

B.4.3 Patent Data

Patent data have been frequently used as an indicator of innovative activity, although such data have serious limitations. For example, Kamien and Schwartz (1975) have noted that many important innovations are not patented, that the patent owner may not be the original innovator, and that the patent data do not differentiate between product and process changes. Furthermore, patenting practices differ by sector and change over time within a sector. In the chemical industry, trade secrets are often preferred to patents, although this may more frequently occur for processes than for products.

These problems all distort the meaning of patent measures so that they are not an accurate reflection of innovative output. However, as noted by Kamien and Schwartz (1975), "systematic study of patenting behavior has led Smookler, Scherer and others to conclude that the number of patents granted to a firm is a usable proxy for inventive outputs." If interpreted with care, patent data may be useful in assessing trends in innovation in a sector over relatively short time periods and in making gross comparisons between sectors.

Patents have been used recently as a measure of chemical innovation by ADL and by the U.S. Patent Office. According to ADL's review of patent activity classified according to SIC codes, industrial organic chemicals dominate the new chemical innovation process. Cyclic crudes and intermediates account for 28% of organic chemical production, which is about 18% of all chemical innovation.

The U.S. Patent and Trademark Office (1979) has produced data on patent activity for its Top 50 chemical subclasses ranked by the rate of growth of the number of patents, the percent growth, and the foreign share. Actual growth is dominated by pharmaceuticals; after eliminating these, growth is largest in organic chemicals (24%) including cyclic intermediates and synthetic resins. However, the rate of increase of patents for pharmaceuticals, which account for the greatest number of chemical patents, has leveled off. Fifty percent of the fastest growing areas are carbon compound products - mostly cyclic intermediates. Process improvements account for most of the remaining activity. The largest foreign patenting area is in dying polyester fibers.

B.5 Chemical Industry Trends That May Affect Innovation

The chemical industry is presently experiencing major shifts in its business environment. The industry is responding and adapting to many changes in its environment of which TSCA is only one. These shifts include increasing world-wide competition, rapidly escalating feedstock prices, depletion of feedstocks, and the obligations a major industry has to society. (C&E News, 1978) The strategies selected by the companies to cope with these changes will in part, determine their potential for innovative developments in the future.

Increasing world-wide competition in chemicals originates from two sources: the large petroleum companies that are diversifying into chemical production and the oil producing nations that are building petrochemical plants. (Maisel, 1980; C&E News, 1979b) Some U.S. analysts have predicted that oil producing countries will link chemical purchases to oil purchases, and that they may dump ammonia and methanol on the world market. (Webber, 1979) Two strategies are being adopted by the U.S. chemical industry in response to these pressures.

The chemical and petrochemical producers are responding to pressure from the oil producing nations by seeking greater efficiency through process improvements for existing products. (Verespecj, 1979) For example, developments in new catalysts are being pursued. (Burke, 1979) The emphasis is on running firms efficiently and on planning and managing research to obtain the best economic gain.

It is expected that the industry will grow more slowly for the remainder of this century, and that new products will evolve from older ones with fewer major new products being produced. (Chemical Week, 1977) Some analysts believe that the growth areas will be in plastics and in the replacement of natural products by synthetics. (Maisel, 1980) Specialty products will continue to outperform the rest of the industry, with emphasis on chemicals for the electronic and energy industries. (Chemical Week, 1979a)

An economic downturn is currently not a major concern to chemical company officials since they do not have excess capacity or significant new production capacity coming on line in the next several years. (Keifer, 1979) Also, the export market will continue to be profitable since the major petroleum producing nations are not yet on the scene, and since U.S. natural gas prices have not climbed as rapidly as petroleum prices for European and Japanese producers. This feedstock price difference gives the U.S. a world-wide price advantage. (Business Week, 1980)

The feedstock problem, however, will not go away. Petroleum is becoming more expensive and scarce; natural gas, although plentiful at present, will not sustain chemical producers in the U.S. forever. substitutes for these feedstocks are available and will play a major role in the industry over the next 30 years. (Landau and Brown, 1978) Coal, although not predicted to be a major source of chemicals for 20 years or more, is expected to play the largest role in replacing petroleum and natural gas. Eastman Kodak has already announced plans to construct an acetic anhydride plant using coal as the feedstock. (C&E News, 1980) Biomass will also be explored both as a feedstock and as a natural source of complex chemicals.

The chemical industry is also being influenced by the changing public perception of the obligations of industry to society. This is reflected, for example, in state and local recognition and regulation of hazardous material handling, production, and disposal; and in the more active role taken by public interest groups in legislation controlling corporate activity that has developed over the last ten years. The industry is also being affected by increases in product liability suits, tort suits, workers compensation requirements, and efforts to increase corporate disclosure.

To respond to these many changes, major capital investments and improvements in chemical process technologies will be essential. Over the next 30 years, the chemical industry will adopt new production processes and will produce improvements on today's products. The future of the industry will be characterized by slower growth and by more careful research investment, regardless of regulatory requirements.

B.6 Major Findings

- The complex process of technological innovation in industry involves activities ranging from basic research and invention to marketing and adoption. Organized R&D is only one element in the process.
- Despite the existence of several partial studies, there is no authoritative source for the rate, direction, and nature of chemical innovation.
- The rate and nature of chemical innovation can be expected to vary greatly among the sectors of the chemical industry. Small firms and new entrants play an important, though largely unmeasured role in innovation, especially in newer or more rapidly developing sections.

- Small firms, in sectors of the industry that have low concentration ratios or that are dominated by large firms, may encounter more trouble meeting TSCA cost increases than other firms.
- As firms become mature their R&D efforts become more risk-averse, process change becomes more important, and they face displacement if they do not recognize the need for continued innovation.
- Established chemical firms have demonstrated a shift toward process change, product modification, and new uses for old products.
- Large firms in the industry have traditionally been best at product modification and process innovation, but not at product discovery.
- Small innovative firms are more dependent on new products, and are therefore more likely to be adversely affected if regulation inhibits the development of new products than are large firms.
- Chemical firms face a variety of challenges including high energy costs, foreign competition, vigorous entry by oil companies, a maturing technology and capital base, and changing public perceptions of the social responsibilities of industry. Regulation, and especially TSCA, is only a part of this challenge.

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APPENDIX C:
DETAILED LIST OF CRITERIA FOR ASSESSING INDIVIDUAL REGULATORY PROGRAMS

1.0 Criteria I -- Capacity to Countervail - Capacity of Alternative to Offset the Unwanted Impacts of TSCA Regulation

  1.1 Criteria 1-1 -- Amount of Resources Directly or Indirectly Allocated - In Relation to Size of Unwanted TSCA Impacts

  1.2 Criteria 1-2 -- Locus of Countervailing Impact in Relation to Locus of TSCA-Related Impact

    1.2.1 Sectoral Locii

      1.2.1.1 General Chemical Industry

      1.2.1.2 Selected Firms (e.g., small firms or firms with history of low volume production)

      1.2.1.3 A Selected Firm (e.g., one chosen with certain characteristics for a test case)

    1.2.2 Chemical Locii

      1.2.2.1 Class of Products (e.g., all catalysts)

      1.2.2.2 Chemical Compounds (e.g., all synthetic resins from phenols or phenoxides with resinifiable amine or amide)

    1.2.3 Firm and Market Cost/Impact Locii

      1.2.3.1 Premanufacturing Notification Costs

      1.2.3.2 Testing Costs

      1.2.3.3 Product Liability Costs (or savings)/Chemical Safety

      1.2.3.4 R&D Costs

      1.2.3.5. Delay Costs

      1.2.3.6 Other Manufacturing Costs

      1.2.3.7 Market Valuation of Safety and Cost Passthrough

1.2.3.8 Rate of Return/Profit on Regulated/Unregulated Chemicals
1.2.3.9 Market Structure/Concentration (rates of entry and exit)
1.2.3.10 Factor Prices (production factors)
1.2.3.11 Workforce Costs
1.2.3.12 Productivity decreases (increases)
1.2.3.13 Innovation (and attendant firm/market effects)

1.2.4 Public Cost/Impact Locii (welfare economic effects)

1.2.4.1 Employment (jobs)
1.2.4.2 Safety/Health
1.2.4.3 Changes in Prices due to Changes in Market Structure
1.2.4.4 Changes in Prices due to Changes in Productivity
1.2.4.5 Changes in Prices Availablility due to Changes in Innovation
1.2.4.6 International Trade/Comparative Advantages

1.3 Specific Considerations Related to the Class of Alternative (four general classes of alternatives which have distinctly different countervailing characteristics)

1.3.1 Preventative - Alternative Acts to Negate the Effects of TSCA Related Regulations by Bringing About Changes in the Public Sector, to Change the Impact of the Regulations Themselves. (For example, if regulations of new entities occurred such that existing products were overly favored, a preventative alternative would be one that redressed the balence in the regulation of new and old chemicals.)

1.3.2 Direct Remedial - Acts to Negate a TSCA Related Effect by Directly Countervailing that Effect Within the Private Sector (e.g., if lower revenues "cause" a decrease in innovation, subsidizing R&D budgets within the firms constitutes a direct mechanism).

1.3.3 Indirect Remedial - Aid Indirectly Offsets Impacted Regulation. (It may be difficult of directly countervail against a negative impact of regulation and more facile to aid some other aspects of the chemical industry where the aid indirectly offsets the regulative impact.

1.3.4 External Remedial - Mechanisms which Act to Ameliorate the Welfare Impacts of TSCA Effects without Trying to Prevent the Private Sector Changes which Give Rise to Them. (E.g., lower revenues result in loss of employment. Increased employment benefits for chemical workers constitutes an externally acting program.)

2.0 Criteria 2 -- Cost Effectiveness

2.1 Criteria 2-1 -- Degree of Reliance on Market Mechanisms
2.2 Criteria 2-2 -- Size of Bureaucracy Needed to Administrate
2.3 Criteria 2-3 -- Size of Other Transaction Costs (e.g., private administration costs)
2.4 Criteria 2-4 -- Lag Time and Startup Costs
2.5 Criteria 2-5 -- Amount and Accuracy of Information Needed for Coordination -- How automatic is the mechanism
2.6 Criteria 2-6 -- Extent to Which Resources can be Diverted from Target
2.7 Criteria 2-7 -- Extent to Probable Effects on Target Area due to Leveraging

3.0 Criteria 3 -- Feasibility

3.1 Criteria 3-1 -- Administrative Feasibility -- Public, Private

3.1.1 Budget Constraints
3.1.2 Personnel Constraints
3.1.3 Time Constraints

3.2 Criteria 3-2 -- Institutional Feasibility -- Public

- 3.2.1 Legal Authority
- 3.2.2 Existing Modus Operandi and Focus of Regulatory Agency
- 3.2.3 Private Sector Behavior
- 3.2.4 Linkages with Other Institutions
- 3.2.5 Precedents

3.3 Criteria 3-3 -- Political Feasibility

- 3.3.1 Feasibility of Obtaining New Legislation (if required)
- 3.3.2 Public and Industry Reaction to Legislation
  - (a) Level of Expenditures
  - (b) Restriction of Freedom, Other Rights

4.0 Criteria 4 -- Uncertainty and Risk

- 4.1 Criteria 4-1 -- Possibility that Purpose may be Thwarted
- 4.2 Criteria 4-2 -- Reliance on Unpredictable Behavior
- 4.3 Criteria 4-3 -- Possible Delays/Litigation
- 4.4 Criteria 4-4 -- Probability of Political/Legisilative Modification
- 4.5 Criteria 4-5 -- Number of Programs with Similar Target (size of portfolio)

5.0 Criteria 5 -- Equity

- 5.1 Criteria 5-1 -- Distribution of Benefits Among Firms
- 5.2 Criteria 5-2 -- Distribution of Costs Among Chemical Industry/Consumers/Taxpayers
- 5.3 Criteria 5-3 -- Distribution of Benefits (or Costs) Between Chemical Producers and Supply Factors (i.e., multi-market equity)

6.0 Criteria 6 -- Dynamic Effects

- 6.1 Criteria 6-1 -- Opportunity Costs of the Government Action - What Other Goals and Programs will have to be Foregone as a Result of Adopting the Program
- 6.2 Criteria 6-2 -- Will the Program "Over Compensate" - Will the Stimulus be so Large that the Original Safety and Health Aim of TSCA Regulation is Thwarted
- 6.3 Criteria 6-3 -- Serendipitous Effects - Will the Program Produce Socially Desirable Changes in Other Areas
- 6.4 Criteria 6-4 -- Leveraging - Capacity to Produce Systemic, Long-Run Positive Effects
- 6.5 Criteria 6-5 -- Complementarity - To What Extent does the Program Mesh with Other Regulatory Goals, Both of the EPA and Other Agencies
- 6.6 Criteria 6-6 -- Other Long-Run Welfare Consequences

APPENDIX D

SOURCES USED TO IDENTIFY CANDIDATE POLICY OPTIONS

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16. ABSTRACT

The autors conclude, from a review of the theoretical and empirical literature and analysis of its application to the chemical industries, that the impact of TSCA on innovation is not predictable. For a number of reasons, TSCA is as likely to stimulate innovation in some sectors as it is to discourage it in others. There are not enough reliable data to separate the effects of TSCA from historical trends and other factors.

The report recommends a cluster of six policies (chosen from a group of thirty-three that were considered) that could be used together to offset some of the negative impacts on innovation if the government decides this is warranted. The recommended policies are:

- --EPA dissemination of chemical information (in the form of test results or labelling);
- --Instituting generic pre-manufacturing notifications for certain classes of new chemicals;
- --Government support for developing cheaper and more reliable test methods;

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- --A subsidy for testing or compliance costs for new chemical development, either through a grant or a loan program;
- --"Fast track" pre-manufacturing reviews for safe chemicals or major innovations;
- --Government support for education and training of toxicologists and related professionals.

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